

EXHIBIT 6

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

-----:
IN RE: ETHICON, INC. PELVIC :
REPAIR SYSTEM PRODUCTS : MASTER FILE
LIABILITY LITIGATION : No. 2:12-MD-02327
_____:
: MDL 2327
: JOSEPH R. GOODWIN
This document relates : US DISTRICT JUDGE
:
to Wave 11 Cases :
:
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August 7, 2019

Deposition of LAWRENCE LIND, M.D.,
held at 30 Cutter Mill Road, Great Neck,
New York, commencing at 12:57 p.m., on the
above date, before Marie Foley, a
Registered Merit Reporter, Certified
Realtime Reporter and Notary Public.

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| <p>1 A P P E A R A N C E S:</p> <p>2</p> <p>3 WAGSTAFF & CARTMELL LLP</p> <p>4 BY: DAVID C. DeGREEFF, ESQUIRE</p> <p>5 4740 Grand Avenue</p> <p>6 Suite 300</p> <p>7 Kansas City, Missouri 64112</p> <p>8 816.701.1100</p> <p>9 ddegreeff@wcllp.com</p> <p>10 Representing the Plaintiff</p> <p>11</p> <p>12</p> <p>13</p> <p>14 RIKER, DANZIG, SCHERER,</p> <p>15 HYLAND, PERRETTI, LLP</p> <p>16 BY: DIANA KATZ GERSTEL, ESQUIRE</p> <p>17 Headquarters Plaza</p> <p>18 One Speedwell Avenue</p> <p>19 Morristown, New Jersey 07962-1981</p> <p>20 973.538.0800</p> <p>21 dgerstel@riker.com</p> <p>22 Representing the Defendant</p> <p>23</p> <p>24</p> | <p>1 - - -</p> <p>2 E X H I B I T S</p> <p>3 - - -</p> <p>4 NO. DESCRIPTION PAGE</p> <p>5 Lind Notice to Take Deposition 29</p> <p>6 Exhibit 1 of Lawrence Lind, MD</p> <p>7</p> <p>8 Lind Flash drive 30</p> <p>9 Exhibit 2</p> <p>10</p> <p>11 Lind Invoice of Dr. Lind dated 31</p> <p>12 Exhibit 3 August 29, 2017</p> <p>13</p> <p>14 Lind Invoice of Dr. Lind dated 32</p> <p>15 Exhibit 4 July 1, 2019</p> <p>16</p> <p>17 Lind Handwritten Report Index 34</p> <p>18 Exhibit 5 of Dr. Lind</p> <p>19</p> <p>20 Lind Curriculum Vitae of Dr. Lind 68</p> <p>21 Exhibit 6</p> <p>22</p> <p>23</p> <p>24</p> |
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Lawrence Lind, M.D.

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| 6 | Exhibit 11 between Gynecare and North | | 6 | Exhibit 18 between Lawrence Lind and | |
| 7 | Shore University Hospital, | | 7 | Ethicon, Inc. Dated July | |
| 8 | Bates No. ETH.MESH.00412092 | | 8 | 10, 2010, Bates No. | |
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| 11 | Lind Secrecy Agreement dated 307 | | 11 | | |
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| 14 | Lind, MD, Bates No. | | 14 | Lind and Ethicon, Inc. | |
| 15 | ETH.MESH.09464276 to | | 15 | dated August 31, 2010, | |
| 16 | 09464279 | | 16 | Bates No. ETH.MESH.02030557 | |
| 17 | | | 17 | to 02030566 | |
| 18 | Lind E-mail chain ending June 313 | | 18 | | |
| 19 | Exhibit 13 15, 2004, Bates No. | | 19 | Lind EWHU HCP Cognos report run 352 | |
| 20 | ETH.MESH.11003781 to | | 20 | Exhibit 20 11/17/10 | |
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| 5 | Lind Q CDA Log, Bates No. 318 | | 5 | 164 7 | |
| 6 | Exhibit 14 ETH.MESH.15359953 to | | 6 | 164 19 | |
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| <p style="text-align: right;">Page 10</p> <p>1 - - -</p> <p>2 12:57 p.m.</p> <p>3 Great Neck, New York</p> <p>4 - - -</p> <p>5 LAWRENCE LIND, M.D., the Witness herein,</p> <p>6 having been first duly sworn by a</p> <p>7 Notary Public in and of the State of</p> <p>8 New York, was examined and testified as</p> <p>9 follows:</p> <p>10 EXAMINATION BY</p> <p>11 MR. DeGREEFF:</p> <p>12 Q. Good morning, doctor.</p> <p>13 Can you tell us your name?</p> <p>14 A. Lawrence Lind, L-I-N-D.</p> <p>15 Q. And Dr. Lind, you have been</p> <p>16 hired as a general liability expert for</p> <p>17 Ethicon in this litigation.</p> <p>18 True?</p> <p>19 A. Yes.</p> <p>20 Q. Have you also served as a</p> <p>21 case-specific expert for Ethicon in</p> <p>22 various cases in this litigation?</p> <p>23 A. I have.</p> <p>24 Q. How many?</p> | <p style="text-align: right;">Page 12</p> <p>1 TVT-O, TVT-Abbrevio and TVT-Exact.</p> <p>2 Q. Doctor, you've been deposed</p> <p>3 before today?</p> <p>4 A. I had a deposition on the TVT,</p> <p>5 and in medical malpractice cases I've been</p> <p>6 deposed.</p> <p>7 Q. Other than the general</p> <p>8 deposition you gave on the TVT in 2017.</p> <p>9 Is that right?</p> <p>10 A. '17 or '18.</p> <p>11 MS. GERSTEL: It was '17, yes.</p> <p>12 BY MR. DeGREEFF:</p> <p>13 Q. Other than that deposition, have</p> <p>14 you been deposed on any Ethicon mesh</p> <p>15 product?</p> <p>16 A. Prolift.</p> <p>17 Q. And that was also the general</p> <p>18 deposition you gave in 2017?</p> <p>19 A. Yes.</p> <p>20 Q. Have you given any case-specific</p> <p>21 expert depositions on behalf of Ethicon in</p> <p>22 this litigation?</p> <p>23 THE WITNESS: In Tays, right?</p> <p>24 Did we do a deposition in Tays?</p> |
| <p style="text-align: right;">Page 11</p> <p>1 A. About four to -- four to six</p> <p>2 cases.</p> <p>3 Q. Have you ever been hired as an</p> <p>4 expert witness for any other transvaginal</p> <p>5 mesh manufacturer?</p> <p>6 A. No.</p> <p>7 Q. And understanding I'm not asking</p> <p>8 you about consulting. I'm just asking you</p> <p>9 about litigation expert.</p> <p>10 A. No, I have not.</p> <p>11 Q. Do you have an understanding of</p> <p>12 what you were hired to do on behalf of</p> <p>13 Ethicon in this litigation?</p> <p>14 A. Yes.</p> <p>15 Q. What is that?</p> <p>16 A. To give opinions regarding</p> <p>17 efficacy and safety of mesh and sling</p> <p>18 products.</p> <p>19 Q. Any particular mesh and sling</p> <p>20 products, or just mesh and sling products</p> <p>21 generally?</p> <p>22 A. So by that you mean did I</p> <p>23 dedicate a deposition on the TVT where</p> <p>24 we're talking about the sling family,</p> | <p style="text-align: right;">Page 13</p> <p>1 MS. GERSTEL: That was in New</p> <p>2 Jersey. The Carolyn Tays matter in</p> <p>3 New Jersey.</p> <p>4 BY MR. DeGREEFF:</p> <p>5 Q. So I think the answer is yes,</p> <p>6 you've been deposed before?</p> <p>7 A. Yes, in one case.</p> <p>8 MS. GERSTEL: Could I just state</p> <p>9 for the record that the 2017</p> <p>10 deposition that Dr. Lind gave, it was</p> <p>11 on TVT and Gynemesh, actually. Not</p> <p>12 Prolift.</p> <p>13 MR. DeGREEFF: Okay.</p> <p>14 BY MR. DeGREEFF:</p> <p>15 Q. Have you ever been deposed</p> <p>16 previously as an expert for any other</p> <p>17 transvaginal mesh manufacturer?</p> <p>18 A. There was a communication</p> <p>19 between myself and I was working on</p> <p>20 research and development for a vaginal</p> <p>21 mini sling for Boston Scientific, and some</p> <p>22 of the feedback I gave in a research lab</p> <p>23 was of interest to the counsels. So I was</p> <p>24 deposed to answer questions regarding my</p> |

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| <p style="text-align: right;">Page 14</p> <p>1 feedback on -- at the research phase of a 2 mini sling. 3 Q. And what was the mini sling 4 product? 5 A. At the time, I don't recall. I 6 don't know if it was named at the time. 7 It was early in the research and 8 development. 9 Q. So you were deposed in the 10 Boston Scientific transvaginal mesh 11 litigation? 12 A. Yes. 13 Q. What was the subject matter of 14 that deposition? 15 A. It was my positive and negative 16 feedback for improvements and design on 17 the device at a research and design lab. 18 Q. The design of a Boston 19 Scientific product. 20 Is that right? 21 A. Yes. 22 Q. What was your involvement in the 23 design of that Boston Scientific product? 24 A. They -- the phase that they had</p> | <p style="text-align: right;">Page 16</p> <p>1 Q. Are those two positives you just 2 pointed out, are those design aspects of 3 any of the TVT slings? 4 MS. GERSTEL: Object to form. 5 A. You know, I don't use mini 6 slings presently. So I haven't been 7 looking at them and comparing them for 8 quite a number of years. It's within the 9 aspect of slings that I look at, I don't 10 have comparisons. 11 Q. Well, the TVT mini slings -- the 12 TVT-S, which is the Ethicon mini sling, is 13 off the market. 14 Right? 15 A. Yes. 16 Q. So you wouldn't be using 17 something that's off the market? 18 A. Correct. 19 Q. And my question was the mini 20 slings you're talking about, for example 21 the handles, are the handles on the TVT 22 products similar? 23 MS. GERSTEL: Object to form. 24 A. I haven't seen them for several</p> |
| <p style="text-align: right;">Page 15</p> <p>1 prototypes for, they asked me to use the 2 device on cadavers and comment on the 3 handling, the ease of placing the sling, 4 potential improvement, potential problems, 5 things that could be improved. 6 Q. And you pointed out problems. 7 Is that right? 8 MS. GERSTEL: Objection. 9 A. I pointed out beneficial aspects 10 and areas that I thought might be 11 improved. 12 Q. What were the beneficial aspects 13 of the Boston Scientific sling that you 14 pointed out? 15 A. I thought the shape of the 16 handle was favorable for being able to 17 plant the anchor at a good angle to the 18 obturator membrane. I thought they had 19 some -- a line at the midline I thought 20 was very helpful in helping to keep the 21 sling 50 percent on each side. 22 And the remainder of the 23 positive and negatives I don't recall. 24 This was about five years ago.</p> | <p style="text-align: right;">Page 17</p> <p>1 years. So I wouldn't have enough recall 2 to compare them. 3 Q. Well, do you currently use TVT 4 products, TVT sling products? 5 A. Yes. 6 Q. What about the aspect you were 7 talking about with the midline -- 8 MR. DeGREEFF: Strike that. 9 Q. So, this was a transobturator 10 placement device. 11 Is that right? 12 A. Yeah. With the mini slings, 13 it's the -- you're placing it to the 14 transobturator membrane without 15 perforating it completely. So it does go 16 to the obturator membrane, but not through 17 it. 18 Q. Is it a good or bad thing to go 19 through the transobturator membrane? 20 MS. GERSTEL: Object to the 21 form. 22 A. The key aspect in designing the 23 mini slings as I do recall giving input, 24 is that you've got to get the anchor set.</p> |

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| <p style="text-align: right;">Page 18</p> <p>1 So it's got to go through -- you know, 2 there's an interior and a posterior aspect 3 of the obturator membrane with the muscle 4 between it. So you have to get through 5 the internal membrane for the anchor to be 6 seated nicely. Otherwise it will pull 7 out. 8 Q. Right. 9 I think you told me you've given 10 one general liability deposition on the 11 TVT and Gynecare product on behalf of 12 Ethicon and four to five case-specific 13 depositions on behalf of Ethicon 14 previously. 15 Is that correct? 16 A. Those are case reports. 17 MS. GERSTEL: Objection. 18 A. They have not gone to 19 deposition. 20 MR. DeGREEFF: Strike that. My 21 fault. 22 Fair point. 23 THE WITNESS: Okay. 24</p> | <p style="text-align: right;">Page 20</p> <p>1 expert in med-mal cases? 2 A. I would say two or three cases a 3 year for the last ten years. 4 Q. So 20 to 30 total probably? 5 A. Yes. 6 Q. Of those 20 to 30, how many have 7 been on behalf of the plaintiff, the 8 injured party? 9 A. Two. 10 Q. And what kind of cases were 11 those? 12 A. A woman was in labor and the 13 baby was stuck, and the maneuvers used to, 14 you know, panicked to get the baby out 15 were excruciatingly outside of the usual 16 protocols, and she endured tremendous 17 pelvic floor injury. 18 And the second one was a 19 laparoscopic case with a patient with five 20 or six previous surgeries with a bowel 21 injury. There was steps taken to verify 22 safety of a laparoscopic case in a patient 23 with a difficult abdomen. 24 Q. So, of the 20 to 30 med-mal</p> |
| <p style="text-align: right;">Page 19</p> <p>1 BY MR. DeGREEFF: 2 Q. So, how many depositions have 3 you given total on behalf of TVM 4 manufacturers in litigation brought by 5 women against them claiming complications? 6 MS. GERSTEL: Object to the 7 form. 8 A. So, there's the -- there's the 9 Gynemesh and TVT, there's the one 10 case-specific report, and there's today. 11 Q. Have you ever testified at trial 12 for any manufacturer of transvaginal mesh? 13 A. No. 14 Q. Have you ever been an expert 15 witness in cases unrelated to transvaginal 16 mesh? 17 A. Yes. 18 Q. What kind of cases? 19 A. I take malpractice cases, both 20 plaintiff and defendant cases, for various 21 law firms in the area that know me and 22 decide when the problem of interest is in 23 my area. 24 Q. How many times have you been a</p> | <p style="text-align: right;">Page 21</p> <p>1 cases you've been an expert in, only two 2 of them you're the plaintiffs' expert? 3 A. Correct. 4 Q. Is it fair for me to assume you 5 understand how this process works, the 6 deposition process, so we don't have to go 7 through the rules? 8 A. Absolutely. 9 Q. Okay. 10 A. I will be a good exchange 11 partner in this process. 12 Q. Perfect. 13 Sir, have you ever been sued? 14 A. I had -- as a resident, I was 15 named in three cases. And one of them 16 settled. The settling had nothing to do 17 with my role in the case. And the other 18 two I got dropped. 19 And since that time, I have not 20 been sued. 21 Q. What was the claim -- were the 22 three cases like companion cases or 23 something? 24 A. One was a very difficult case</p> |

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| <p style="text-align: right;">Page 22</p> <p>1 with a mother came in sepsis in labor with 2 twins in labor, and it was clear that she 3 was septic. The vaginal delivery went 4 routinely, but the high risk maternal 5 fetal medicine doctor was suspicious that 6 she probably had group A strep and was in 7 tremendous danger of serious 8 complications, and both she and the baby 9 died.</p> <p>10 Q. What were the allegations 11 against you in that case?</p> <p>12 A. I don't -- they never questioned 13 me for anything I did wrong. I think they 14 wanted to know what my role was in surgery 15 to see if I was more involved with 16 something that might be tangible to the 17 outcome. And I assisted with the delivery 18 as a second hand. So my role was felt to 19 be minimal.</p> <p>20 The second one was a patient had 21 a abnormal bleeding after a C-section, and 22 I was called with the GYN oncology team to 23 help do some artery ligation to reduce 24 bleeding, and in the process of the</p> | <p style="text-align: right;">Page 24</p> <p>1 accurate as possible. 2 Is that fair?</p> <p>3 A. Yes.</p> <p>4 Q. And you want to be as thorough 5 in your review of the available 6 information, documents and literature as 7 possible.</p> <p>8 Correct?</p> <p>9 A. Yes.</p> <p>10 Q. And you wanted to make sure you 11 got all of the information and considered 12 all the information that was pertinent to 13 your opinions, right?</p> <p>14 MS. GERSTEL: Object to the 15 form.</p> <p>16 A. I would describe that -- the 17 answer to your question is yes. However, 18 as these interviews or depositions 19 continue, areas of interest where the 20 other party feels I have not been as 21 thorough have come to attention. So I 22 have continued my research and continued 23 my reading and added to my knowledge and 24 resources to be able to be more complete</p> |
| <p style="text-align: right;">Page 23</p> <p>1 procedure, the femoral nerve was 2 compressed. So she had some lack of 3 sensation in the -- you know, we saved 4 her -- well, may have saved her life. We 5 controlled the bleeding, but in the 6 process of controlling the bleeding, we 7 kinked and caused some pressure on one -- 8 the nerves to the vessels of one of her 9 legs. It was diagnosed in the recovery 10 room and she had to go back and have that 11 released, but she did fine, but she did 12 have to go back.</p> <p>13 Q. When you serve as an expert in a 14 case, is it your goal to promote the 15 truth?</p> <p>16 A. Yes.</p> <p>17 Q. And not to be an advocate or 18 promoter for one side or the other?</p> <p>19 A. Correct.</p> <p>20 Q. You agree that an expert's 21 opinion should be unbiased and objective?</p> <p>22 A. I agree.</p> <p>23 Q. When you gave your opinions in 24 this litigation, you wanted to be as</p> | <p style="text-align: right;">Page 25</p> <p>1 than I was even at the time of the report. 2 Q. So, you reviewed additional 3 information after you had already issued 4 your opinions?</p> <p>5 A. Yes.</p> <p>6 MS. GERSTEL: Objection. 7 BY MR. DeGREEFF:</p> <p>8 Q. And did you change your opinions 9 based on any of that additional 10 information?</p> <p>11 A. No.</p> <p>12 Q. I take it what you actually did 13 was just add some stuff to your reliance 14 list.</p> <p>15 Is that fair?</p> <p>16 MS. GERSTEL: Object to form.</p> <p>17 A. Well, things were added to the 18 reliance list and some were just added to 19 my general knowledge just to enable me to 20 be more informed on issues that were 21 brought to my attention that I had 22 authority on, but not as much authority on 23 as I would like to to be authoritative at 24 a higher level.</p> |

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| <p style="text-align: right;">Page 26</p> <p>1 Q. So following depositions, you 2 went and educated yourself better for the 3 next deposition, is what you did? 4 MS. GERSTEL: Object to the 5 form. 6 A. I had interest in being educated 7 for the sake of being educated and 8 knowledgeable for my practice and 9 teaching, as well as for the depositions, 10 yes. 11 Q. Did you want to make sure you 12 had an understanding of both sides of the 13 story before you gave your opinions? 14 A. Yes. 15 Q. The relevant information that 16 you'd want to consider when rendering your 17 opinions would include Ethicon internal 18 documents. 19 Is that fair? 20 MS. GERSTEL: Object to the 21 form. 22 A. That's a piece amongst a much 23 larger group of documents, which is 24 scientific literature. But those would be</p> | <p style="text-align: right;">Page 28</p> <p>1 physician to promote a position that 2 jeopardizes the health or safety of his 3 patients? 4 A. I'm sorry. Could you repeat 5 that? 6 Q. Would it be unfair for a 7 physician to promote a position that is 8 adverse or could jeopardize the health or 9 safety of his patients? 10 MS. GERSTEL: Object to the 11 form. 12 A. If the information he was given 13 was incorrect, that would not be 14 appropriate. 15 Q. I think we're saying the same 16 thing, but I'm not sure. Let me ask -- 17 A. I'm not sure either. 18 Q. Let me ask my question again. 19 A physician shouldn't -- 20 MR. DeGREEFF: Let me ask it 21 maybe in a easier way. 22 Q. A physician should not promote a 23 position that is adverse to the health, 24 safety and welfare of their patients.</p> |
| <p style="text-align: right;">Page 27</p> <p>1 included, yes. 2 Q. Sure. 3 And it would also include 4 medical literature? 5 A. Sure. 6 Q. Would also include standards and 7 testing performed on the products? 8 A. Yes. 9 Q. Would it include making sure you 10 understand the differences between the 11 products? 12 A. Yes. 13 Q. Do you agree that opinions 14 should be able to be substantiated by the 15 totality of the most relevant available 16 data and information? 17 MS. GERSTEL: Object to the 18 form. 19 A. Yes. 20 Q. As a physician, your patient's 21 safety is the most important thing. 22 Fair? 23 A. Yes. 24 Q. And would it be unfair for a</p> | <p style="text-align: right;">Page 29</p> <p>1 Is that fair? 2 MS. GERSTEL: Object to the 3 form. 4 A. I can agree with that. 5 MR. DeGREEFF: Let's do some 6 housekeeping and mark some of this 7 stuff you brought with you here. 8 (Lind Exhibit 1, Notice to Take 9 Deposition of Lawrence Lind, MD, was 10 marked for identification, as of this 11 date.) 12 BY MR. DeGREEFF: 13 Q. Dr. Lind, I'm going to hand you 14 what I marked as Deposition Exhibit 1. 15 That is the notice for your deposition 16 today. 17 Have you seen that before? 18 A. Yes. 19 Q. When did you first see it? 20 A. A few weeks ago, a month ago. 21 Q. Who provided it to you? 22 A. Diana. 23 Q. That would be counsel for 24 Ethicon that's here with you today?</p> |

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| <p style="text-align: right;">Page 30</p> <p>1 A. Counsel for Ethicon.</p> <p>2 Q. And did you bring -- in fairness</p> <p>3 to you, so, you've brought some things</p> <p>4 with you today.</p> <p>5 Correct?</p> <p>6 A. Yes.</p> <p>7 MR. DeGREEFF: One of the things</p> <p>8 is a flash drive, and I'm going to</p> <p>9 mark it as deposition Exhibit 2.</p> <p>10 (Lind Exhibit 2, flash drive,</p> <p>11 was marked for identification, as of</p> <p>12 this date.)</p> <p>13 BY MR. DeGREEFF:</p> <p>14 Q. Can you tell me what is on this</p> <p>15 flash drive?</p> <p>16 A. That is a reliance list.</p> <p>17 Q. So this would be all of the</p> <p>18 materials that are identified on the</p> <p>19 reliance list?</p> <p>20 A. Those are all the materials on</p> <p>21 the existing reliance list. There are</p> <p>22 materials that I reviewed since that was</p> <p>23 created that are in my head that are also</p> <p>24 part of my knowledge and information I</p> | <p style="text-align: right;">Page 32</p> <p>1 statements regarding the defense expert</p> <p>2 report on TVT and TVT-Exact.</p> <p>3 Q. So is that one of your invoices</p> <p>4 with regard to preparation of your TVT</p> <p>5 products expert report?</p> <p>6 A. Yes.</p> <p>7 Q. The general report, correct?</p> <p>8 A. This would be the report we're</p> <p>9 looking at today.</p> <p>10 Q. Correct.</p> <p>11 And this would be the bill for</p> <p>12 the report regarding the general liability</p> <p>13 opinions you're giving in the litigation</p> <p>14 as a whole.</p> <p>15 Fair?</p> <p>16 Not case-specific.</p> <p>17 A. Yes.</p> <p>18 (Lind Exhibit 4, invoice of Dr.</p> <p>19 Lind dated July 1, 2019, was marked</p> <p>20 for identification, as of this date.)</p> <p>21 BY MR. DeGREEFF:</p> <p>22 Q. Then can you tell me what</p> <p>23 Exhibit 4 is, please, doctor?</p> <p>24 A. This is a bill for a</p> |
| <p style="text-align: right;">Page 31</p> <p>1 would share today that are not on the</p> <p>2 reliance list.</p> <p>3 Q. Okay. We're going to get to</p> <p>4 that in a minute. I just want to make</p> <p>5 sure I understand what's on the flash</p> <p>6 drive.</p> <p>7 The flash drive includes</p> <p>8 everything that's on the written</p> <p>9 supplemental exhibit list.</p> <p>10 Fair?</p> <p>11 A. Yes.</p> <p>12 Q. Then you brought a couple other</p> <p>13 things with you that appear to be</p> <p>14 invoices.</p> <p>15 Is that correct?</p> <p>16 A. Yes.</p> <p>17 (Lind Exhibit 3, invoice of Dr.</p> <p>18 Lind dated August 29, 2017, was marked</p> <p>19 for identification, as of this date.)</p> <p>20 BY MR. DeGREEFF:</p> <p>21 Q. Can you tell me what Exhibit 3</p> <p>22 is, doctor?</p> <p>23 A. This is an invoice for review of</p> <p>24 relevant literature and summary of opinion</p> | <p style="text-align: right;">Page 33</p> <p>1 case-specific report. The case-specific</p> <p>2 report appears to be an error. This is</p> <p>3 additional records that were reviewed for</p> <p>4 this preparation.</p> <p>5 Q. Okay. So, Exhibit 4 is an</p> <p>6 additional invoice for review of records</p> <p>7 related to your general report on the TVT</p> <p>8 products.</p> <p>9 Fair?</p> <p>10 A. Yes.</p> <p>11 Q. So, it says case-specific, but</p> <p>12 that's an error.</p> <p>13 A. Yes.</p> <p>14 Q. It should be generic report?</p> <p>15 A. Correct.</p> <p>16 Q. Is there anything else that you</p> <p>17 brought with you today?</p> <p>18 A. I have my general report as it</p> <p>19 was served to you.</p> <p>20 Q. Okay.</p> <p>21 A. I prepared just an index. It</p> <p>22 just helps me when you ask me about a</p> <p>23 certain topic, it lets me go to a spot in</p> <p>24 my report more quickly.</p> |

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| <p style="text-align: right;">Page 34</p> <p>1 I have a 2008 and a 2015 IFU. 2 And I have the articles that are 3 referenced in my report. 4 And I have an index of those 5 articles so I can go to them quickly when 6 we want to discuss them. 7 Q. Is everything you have in front 8 of you included on the flash drive? 9 A. I believe it is. And the flash 10 drive probably has more articles than are 11 here. 12 Q. Is the index included on the 13 flash drive? 14 THE WITNESS: I don't know the 15 answer to that. 16 MS. GERSTEL: It should be, but 17 I can confirm that. 18 MR. DeGREEFF: It's okay. Let's 19 just go ahead and mark it. 20 (Lind Exhibit 5, handwritten 21 Report Index of Dr. Lind, was marked 22 for identification, as of this date.) 23 MR. DeGREEFF: And I'll let you 24 continue to use it, obviously.</p> | <p style="text-align: right;">Page 36</p> <p>1 disclosure, sometimes when we go to the 2 report, we will go to an area of the 3 report and the key thing's going to be to 4 discuss what's in that section. So 5 sometimes I have written maybe three words 6 that reminds me of what the study is 7 talking about in that section. My goal 8 there is to get to that and I say let me 9 go to the study, and we've got to go 10 through the binders and find it and locate 11 it and I want to review it. I can save us 12 that time. 13 So there are a few words here 14 and there that just remind me of what an 15 article said. 16 Q. Okay. Fair enough. 17 So, sir, this is a pretty simple 18 question. 19 You're being paid to serve as a 20 expert witness for Ethicon in this 21 litigation. 22 True? 23 A. Yes. 24 Q. And, so, other than Exhibit 3</p> |
| <p style="text-align: right;">Page 35</p> <p>1 THE WITNESS: Do you want a copy 2 so you have one to keep? 3 MR. DeGREEFF: No, that's okay. 4 BY MR. DeGREEFF: 5 Q. Doctor, I've marked Deposition 6 Exhibit 5. 7 Can you tell me what that is? 8 A. It's a long report, you know, 9 50-plus pages, and we're here to have a 10 several-hour discussion about what's in 11 the report, amongst other things you may 12 want to discuss. And it was -- I found 13 from the past experience that hunting for 14 areas that we're talking about is useful 15 to just have a one-page thing that lets me 16 go to the spot a little more quickly. 17 Q. Okay. So, this is 18 essentially -- Exhibit 5 is essentially a 19 skeleton outline of your report so that 20 you can -- 21 A. Right. 22 Q. -- find things more quickly? 23 A. Right. 24 Now, I will say, for complete</p> | <p style="text-align: right;">Page 37</p> <p>1 and Exhibit 4, have you sent any bills for 2 your work on the TVT product general 3 expert report? 4 A. Let me just -- may I just see 5 those one more time? 6 Q. (Hanging.) 7 A. (Perusing document.) 8 I have not. 9 Q. Have you incurred any more time 10 to date that you have not billed for yet? 11 A. Yes. 12 Q. About how much time is that? 13 A. About 25 hours. 14 Q. Will you be billing that 25 15 hours at \$500 an hour? 16 A. I will. 17 Q. And is \$500 an hour your rate? 18 A. Yes. 19 Q. What is your rate for the 20 deposition here today? 21 A. Seven thousand five hundred. 22 Q. So it's 7,500 is your rate for a 23 full-day deposition. 24 Is that correct?</p> |

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| <p style="text-align: right;">Page 38</p> <p>1 A. Yes, it is.</p> <p>2 Q. Okay. So, check my math, but</p> <p>3 that's about another \$20,000?</p> <p>4 A. About right.</p> <p>5 Q. So that would be initially to</p> <p>6 the 10,500 and 16,000 that are set forth</p> <p>7 in Exhibits 4 and 3?</p> <p>8 A. Yes.</p> <p>9 Q. So that's, what? \$46,500,</p> <p>10 roughly, that you've billed -- that you</p> <p>11 will have billed to date once those</p> <p>12 invoices go out for your work on the TVT</p> <p>13 general expert report?</p> <p>14 A. Yes.</p> <p>15 Q. How much did you --</p> <p>16 MR. DeGREEFF: Strike that.</p> <p>17 Q. Did you do any additional report</p> <p>18 related to the Gynecare mesh products?</p> <p>19 By that I mean I guess the POP</p> <p>20 products.</p> <p>21 A. We have a Gynemesh general</p> <p>22 report.</p> <p>23 Q. And was that also done in this</p> <p>24 litigation for Ethicon?</p> | <p style="text-align: right;">Page 40</p> <p>1 Q. When were you first approached</p> <p>2 to serve as an expert for Ethicon in the</p> <p>3 transvaginal mesh litigation?</p> <p>4 A. About three-and-a-half years</p> <p>5 ago.</p> <p>6 Q. My math's not very good, but</p> <p>7 would that be the beginning of 2016?</p> <p>8 A. Somewhere in the 2016.</p> <p>9 Q. And you've also done multiple</p> <p>10 case-specific expert reports on behalf of</p> <p>11 Ethicon litigation.</p> <p>12 Right?</p> <p>13 A. Yes.</p> <p>14 Q. Approximately how much have you</p> <p>15 billed them for preparing those reports?</p> <p>16 A. If you put all these together,</p> <p>17 you put everything together, I think we're</p> <p>18 probably in the 200 to \$250,000 range. If</p> <p>19 you put everything you've already, you</p> <p>20 know, kind of itemized and now tried to</p> <p>21 expand to the case-specific, say from when</p> <p>22 I started my relationship with them til</p> <p>23 now for invoices related to pelvic mesh</p> <p>24 expert review and participation, it's 200</p> |
| <p style="text-align: right;">Page 39</p> <p>1 A. Yes.</p> <p>2 Q. And those were general expert</p> <p>3 opinions?</p> <p>4 A. Yes.</p> <p>5 Q. What did you -- how much have</p> <p>6 you billed to date for your work on that?</p> <p>7 A. I don't recall specifically. It</p> <p>8 was two years ago. It would be in the</p> <p>9 same ballpark. Maybe just slightly less</p> <p>10 because it was four products, and I think</p> <p>11 it was a little bit less, but it was in</p> <p>12 the same ballpark.</p> <p>13 Q. So 40 to \$50,000? Somewhere in</p> <p>14 there?</p> <p>15 A. I would say 30 to 50 is the</p> <p>16 range I could support.</p> <p>17 Q. Who would know the exact answer</p> <p>18 to that question?</p> <p>19 A. I could go back to my bank</p> <p>20 records. And am certain that whether it's</p> <p>21 the counsel's office or accounting or</p> <p>22 Gynecare's accounting, I'm sure they would</p> <p>23 have it as well. I know I would have it</p> <p>24 if I reviewed my bank records.</p> | <p style="text-align: right;">Page 41</p> <p>1 to 250,000.</p> <p>2 Q. And that is since the beginning</p> <p>3 of 2016?</p> <p>4 A. Yes.</p> <p>5 Q. I just want to make sure I</p> <p>6 understand what you're saying. I think I</p> <p>7 do.</p> <p>8 So, since you were first</p> <p>9 contacted by Ethicon to serve as an expert</p> <p>10 in this litigation in early 2016, you've</p> <p>11 been paid roughly 200 to \$250,000 for your</p> <p>12 work as an expert witness?</p> <p>13 A. Yes.</p> <p>14 Q. And that would not include any</p> <p>15 consulting work you've done for them. It</p> <p>16 would just be in relation to being a</p> <p>17 litigation expert?</p> <p>18 A. This is everything from 2016 and</p> <p>19 current. Consulting work that I did for</p> <p>20 Ethicon is more than a decade ago. So</p> <p>21 this is excluding what was done in the</p> <p>22 2000 to 2010 was different type of work</p> <p>23 where I was working with them on product</p> <p>24 development and all the slings that we</p> |

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1 discussed.

2 Q. Well, the last time you worked

3 for Ethicon wasn't in 2010.

4 Right?

5 A. I don't recall exactly when. It

6 was probably earlier than that.

7 Q. Well, it was actually later than

8 that.

9 Right?

10 MS. GERSTEL: Object to the

11 form.

12 A. As a consultant?

13 I don't recall precisely.

14 Q. As you sit here right now, do

15 you have any understanding of how much you

16 were paid by Ethicon when working for them

17 under a consulting agreement, master

18 consulting agreement, any other such

19 verbiage they used? Did you have any idea

20 how much they paid you?

21 A. You know, I don't have an

22 accounting on it on hand.

23 I would estimate in the 20 to

24 35,000 range.

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1 Q. Well, in 2011 alone it was over

2 a hundred thousand.

3 Right?

4 MS. GERSTEL: Objection.

5 A. I would have to review that.

6 Q. Okay. We'll get to that.

7 Do you keep any kind of

8 itemization of your time spent on --

9 MR. DeGREEFF: Strike that.

10 Q. So, your invoices are broken

11 down, you know, fairly broadly on

12 Exhibit 3 and 4.

13 Do you have any -- do you submit

14 any kind of a more detailed itemization to

15 Ethicon?

16 A. I don't.

17 Q. Do you have a more detailed

18 itemization?

19 A. The documents that go into

20 making one of those invoices are marked

21 individually. I'll get a binder and I'll

22 go through it and I'll just mark on the

23 front how many hours, and then I take

24 those handwritten totals and make a common

Page 44

1 invoice.

2 Q. Okay. So, is there -- I mean,

3 when you write out your handwritten, do

4 you write out what you did?

5 A. Yeah. I write review of binder.

6 You know, TVT literature, review of

7 literature search on my own, TVT

8 complications. Whatever the category is

9 that I've taken as a meaningful piece of

10 work, I package it and make that a, you

11 know, a time element package that's useful

12 to put a signature on. Or it might be

13 where I have everything I have to look at

14 and I'll go through everything that I have

15 and I'll mark what I've looked at.

16 Q. When you're keeping those notes,

17 do you write down, for example, like if

18 you have a call with defense counsel?

19 A. If I have a what?

20 Q. A call with defense counsel.

21 A. There are some -- there are some

22 invoices that have phone meeting or

23 in-person meeting with counsel.

24 Q. Where are those invoices?

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1 A. I think those are on some of the

2 case-specific and I think on the -- they

3 may be on the invoice for the Gynemesh. I

4 think it includes one preparatory session

5 that was listed, as I recall. I'm not

6 certain of that.

7 MR. DeGREEFF: Have we -- have

8 those been produced?

9 MS. GERSTEL: At his Gynemesh

10 deposition, we produced invoices. I

11 can't tell you specifically what they

12 were, but I know that we did produce

13 invoices at his Gynemesh deposition.

14 MR. DeGREEFF: Okay. What about

15 the case-specific?

16 MS. GERSTEL: The one

17 case-specific deposition that he's

18 had, it was the Tays deposition in the

19 New Jersey litigation, and we did

20 produce invoices related to his work

21 in the Tays matter at that deposition.

22 MR. DeGREEFF: Okay. Yeah,

23 that's our case.

24

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| <p style="text-align: right;">Page 46</p> <p>1 BY MR. DeGREEFF:</p> <p>2 Q. How many hours would you say --</p> <p>3 we'll get to this, but how many hours</p> <p>4 would you say since you started working</p> <p>5 with Ethicon in 2016 that you've spent</p> <p>6 working as an expert witness for them?</p> <p>7 MS. GERSTEL: Objection.</p> <p>8 A. Two hundred thousand divided by</p> <p>9 500. Whatever it is.</p> <p>10 I'm also not great at quick</p> <p>11 math.</p> <p>12 200 to 250,000 divided by 500.</p> <p>13 So 500 times -- 500.</p> <p>14 Q. Five hundred hours or so?</p> <p>15 A. Yeah.</p> <p>16 Q. I guess 400 to 500?</p> <p>17 A. Yeah. Yes.</p> <p>18 Q. And in this litigation --</p> <p>19 MR. DeGREEFF: Strike that.</p> <p>20 Q. In preparation of the report</p> <p>21 we're here about today, which is the TVT</p> <p>22 general report, based on your Exhibit 3</p> <p>23 and Exhibit 4, it looks like you spent</p> <p>24 about 53 hours, plus the 25 that you've</p> | <p style="text-align: right;">Page 48</p> <p>1 searches that I felt were relevant.</p> <p>2 Q. Who drafted the reliance list?</p> <p>3 A. Counsel.</p> <p>4 Q. That's counsel for Ethicon?</p> <p>5 A. Yes.</p> <p>6 Q. I guess when I ask that</p> <p>7 question, to be clear, who drafted the</p> <p>8 supplemental reliance list?</p> <p>9 A. I would come up with more</p> <p>10 articles and would say they're relevant,</p> <p>11 and then they would be added by counsel</p> <p>12 for Ethicon.</p> <p>13 Q. So counsel for Ethicon drafted</p> <p>14 the supplemental reliance list?</p> <p>15 A. Yes.</p> <p>16 Q. So, the other it's like 45, 50</p> <p>17 hours --</p> <p>18 MR. DeGREEFF: Strike that.</p> <p>19 Q. The other 50 hours or so were</p> <p>20 spent in review of the materials on the</p> <p>21 reliance list?</p> <p>22 A. Finding the materials and</p> <p>23 reviewing them, yes.</p> <p>24 Q. Does that 50 hours include any</p> |
| <p style="text-align: right;">Page 47</p> <p>1 spent since then.</p> <p>2 Is that right?</p> <p>3 A. What's on those two plus 25.</p> <p>4 Q. So double check me, but that's,</p> <p>5 what? 78?</p> <p>6 A. 21 and 32 is 53 and 25.</p> <p>7 Yeah, about 78.</p> <p>8 Q. How much of that 78 hours was</p> <p>9 spent --</p> <p>10 MR. DeGREEFF: Strike that.</p> <p>11 Q. How much of that 78 hours was</p> <p>12 spent in actual drafting and preparation</p> <p>13 of the report itself?</p> <p>14 A. One-third.</p> <p>15 Q. 25 to 30 hours?</p> <p>16 A. Yes.</p> <p>17 Q. And the rest of it was spent</p> <p>18 doing what?</p> <p>19 A. Research and reading.</p> <p>20 Q. Did you prepare the reliance</p> <p>21 list?</p> <p>22 A. The reliance list has articles</p> <p>23 provided by counsel, as well as several --</p> <p>24 many, many that I found on my own Pub Med</p> | <p style="text-align: right;">Page 49</p> <p>1 time preparing for your deposition with</p> <p>2 counsel?</p> <p>3 A. Yes. We met twice.</p> <p>4 Q. About how long did you meet each</p> <p>5 time?</p> <p>6 A. Four hours.</p> <p>7 Q. So that's about eight hours</p> <p>8 total?</p> <p>9 A. Yes.</p> <p>10 Q. And when were those meetings?</p> <p>11 A. Last week and the week before.</p> <p>12 Q. Where were they?</p> <p>13 A. They both -- one was here. One</p> <p>14 was in my office.</p> <p>15 Q. That eight hours was included in</p> <p>16 the 78 we discussed earlier.</p> <p>17 Right?</p> <p>18 A. Yes.</p> <p>19 Q. So, more like 40 hours probably</p> <p>20 locating and reviewing the materials in</p> <p>21 the reliance list?</p> <p>22 A. Sounds about right.</p> <p>23 Q. Any phone calls with counsel</p> <p>24 included in that 78 hours?</p> |

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| <p style="text-align: right;">Page 50</p> <p>1 A. One or two brief, minutes, 2 minutes on each.</p> <p>3 Q. During your meetings with 4 counsel, were there any specific documents 5 you were shown?</p> <p>6 A. We went over the -- certainly 7 the two binders here which are the 8 references that relate to my expert 9 report. There were various other -- many, 10 many of the documents from the reliance 11 list.</p> <p>12 I was shown some company 13 documents.</p> <p>14 There was -- we reviewed IFUs.</p> <p>15 Q. So, the binders you referenced 16 are the binders of literature you've got 17 in front of you?</p> <p>18 A. Yes.</p> <p>19 Q. What company documents were you 20 shown?</p> <p>21 A. Testimony by, you know, 22 certainly not comprehensive, by selected 23 administrators in Ethicon and what they 24 had to say about -- in their depositions</p> | <p style="text-align: right;">Page 52</p> <p>1 Q. And then from there, it was 2 selected by defense counsel?</p> <p>3 A. It was kind of a combination of 4 things I was curious about and things she 5 thought would be relevant.</p> <p>6 Q. So, I think the answer to my 7 question is yes. Right? That defense 8 counsel selected some of the documents you 9 were shown?</p> <p>10 MS. GERSTEL: Object to the 11 form.</p> <p>12 A. No. I think the answer is that 13 I requested to see certain types of 14 documents, and she selected others.</p> <p>15 Q. That's the same thing.</p> <p>16 Then there was another category 17 of things you said you reviewed that you 18 were shown.</p> <p>19 What was it?</p> <p>20 We had the binders, the internal 21 documents. I believe there was something 22 else you noted.</p> <p>23 A. There were e-mails, some 24 testimony. Looked at IFUs, which are</p> |
| <p style="text-align: right;">Page 51</p> <p>1 or what they might have said in developing 2 the products, some extracts of e-mails.</p> <p>3 Q. So you were shown some 4 deposition testimony?</p> <p>5 A. Yes.</p> <p>6 Q. You were shown some e-mail 7 extracts?</p> <p>8 A. Yes.</p> <p>9 Q. Anything else?</p> <p>10 A. No, I don't think so.</p> <p>11 Q. Who selected the documents you 12 were shown?</p> <p>13 A. You know, I asked for a few 14 things. I had -- I had -- I asked if -- 15 you know, what documents, you know, have 16 come under scrutiny in other depositions 17 are the ones that I might want to look at, 18 and counsel had some documents that she 19 recommended I see.</p> <p>20 Q. So counsel selected some of the 21 documents and you selected some of the 22 documents?</p> <p>23 A. I said show me -- I said show me 24 the good stuff and show me the bad stuff.</p> | <p style="text-align: right;">Page 53</p> <p>1 company documents, a subset of the company 2 documents.</p> <p>3 Q. What e-mails were you shown?</p> <p>4 A. There were some members of the 5 development team giving opinions as to 6 whether or not a mesh was stiff. There 7 were some e-mails talking about whether a 8 certain design of a sling might cause 9 pain, should we be designing it that way.</p> <p>10 It was a -- certainly a small 11 subset of review as I was told the size of 12 the company documents that existed and the 13 testimonies that were weeks long. So it 14 certainly was not comprehensive.</p> <p>15 Q. These were e-mails and documents 16 by Ethicon employees?</p> <p>17 A. Yes.</p> <p>18 Q. And what did the Ethicon 19 employees have to say about the stiffness 20 of the mesh?</p> <p>21 MS. GERSTEL: Object to the 22 form.</p> <p>23 A. There was concern of differences 24 between machine-cut mesh and laser-cut</p> |

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| <p style="text-align: right;">Page 54</p> <p>1 mesh, and if laser-cut mesh was stiffer, 2 might it be an issue in planning for the 3 products it was planned for use in. 4 Q. So, the Ethicon employees in the 5 materials you reviewed were concerned 6 about laser-cut mesh being stiffer? 7 MS. GERSTEL: Object to the 8 form. 9 A. It was expressed as one of the 10 concerns. 11 Q. And why were they concerned 12 about the stiffness of mesh? 13 A. You know, there was conjecture 14 that if it was stiffer, it might behave 15 differently in clinical performance. 16 Q. So, your understanding of the 17 e-mails you reviewed from the Ethicon 18 employees was that they were concerned 19 that stiffer mesh would lead to more 20 complications. 21 Is that true? 22 A. I don't recall that wording. 23 I do recall them discussing 24 whether it would have relevance to</p> | <p style="text-align: right;">Page 56</p> <p>1 these e-mails are shared, it's an 2 extracted e-mail from a sequence of 3 discussions. 4 Q. Sir, that's not the question 5 that's pending. 6 MR. DeGREEFF: We'll read my 7 question back. 8 (The requested portion of the 9 record was read by the Court Reporter.) 10 A. I think they would be concerned 11 about a change that might be positive for 12 the mesh as well as negative for the mesh. 13 Q. Okay. So, your understanding 14 from those e-mails, just to make sure I 15 understand what you're saying, is that the 16 Ethicon employees were concerned about the 17 efficacy and safety outcomes related to 18 stiffness of mesh. 19 A. Yes. 20 Q. And then you said that you 21 reviewed some e-mails from Ethicon 22 employees related to whether a certain 23 design -- related to certain designs of 24 mesh.</p> |
| <p style="text-align: right;">Page 55</p> <p>1 outcome, which of course would include 2 efficacy and safety, but I don't recall 3 specific wording that it would increase or 4 decrease complications. 5 Q. So they were concerned about 6 whether there would be more negative 7 outcomes with laser-cut mesh because it 8 was stiffer? 9 MS. GERSTEL: Object to the 10 form. 11 BY MR. DeGREEFF: 12 Q. Is that your understanding? 13 A. I'm going to stick to my answer 14 that they were concerned about whether it 15 would change efficacy and safety. Safety 16 would, of course, include any changes in 17 positive or negative outcomes. 18 Q. Well, I mean, someone wouldn't 19 be concerned about a positive outcome. 20 Right? 21 MS. GERSTEL: Object to the 22 form. 23 A. You know, one of the things that 24 I think is important to share is that when</p> | <p style="text-align: right;">Page 57</p> <p>1 Is that correct? 2 A. Yes. 3 Q. When we're talking about 4 laser-cut mesh, some of the TVT products 5 we're here about today are laser-cut mesh. 6 Correct? 7 A. Yes. 8 Q. Which of the TVT sling products 9 use laser-cut mesh? 10 A. The TVT-Exact and the Abbrevo 11 are all laser-cut. The other two are 12 laser cut, mechanically-cut. Some of it's 13 geographic distribution and some of it's 14 physician request. 15 Q. So the TVT and the TVT-O have 16 both laser and mechanic-cut options? 17 A. Yes. 18 Q. So, the e-mails that you were 19 reviewing related to the Ethicon employees 20 discussing design of a product, can you 21 tell me what your understanding was of 22 those e-mails? 23 A. When the obturator, the TVT-O 24 was being designed and developed, the</p> |

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| <p style="text-align: right;">Page 58</p> <p>1 questions, and there were e-mails 2 discussing whether the passage -- the 3 difference in passage would affect, you 4 know, the leg or the groin. I do recall 5 some discussions on that. 6 Q. Okay. So, the -- your 7 understanding was that the Ethicon 8 employees were discussing whether the 9 transobturator approach would lead to 10 increased groin pain. 11 Is that true? 12 MS. GERSTEL: Object to the 13 form. 14 A. I think that was one of the 15 concerns expressed in the e-mails, yes. 16 Q. What other concerns were 17 expressed in the e-mails? 18 MS. GERSTEL: Object to the 19 form. 20 A. I don't recall others that are 21 coming to mind presently. 22 Q. And the transobturator approach 23 is used by the TVT-O and TVT-Abbrevio. 24 Correct?</p> | <p style="text-align: right;">Page 60</p> <p>1 describe increased risk of operation need 2 to be looked at individually because I'm 3 aware -- the answer to your question is 4 yes, but I can't confirm that being a 5 legitimate statement because I have to 6 look at the details of the article because 7 they're very specific as to why they were 8 re-operated on. And the data is mixed. 9 There is not consensus data or data at a 10 high level that suggests that the 11 re-operation rate is two times greater 12 with obturator, but there are reports. 13 Q. So you are aware of the 14 literature stating that? 15 A. Yes. 16 Q. And is that literature contained 17 in your reliance list? 18 A. There's a hell of lot of TVT-O 19 literature in my reliance list. So I 20 believe a lot of it is there, yes. 21 Q. The e-mails we just discussed by 22 the Ethicon employees with regard to the 23 laser-cut mesh or the transobturator 24 placement, are those on your reliance</p> |
| <p style="text-align: right;">Page 59</p> <p>1 A. Correct. 2 Q. Are you aware of literature 3 concerning potential increased risks 4 associated with the transobturator 5 approach versus the retropubic? 6 MS. GERSTEL: Object to the 7 form. 8 A. Yes. 9 Q. And what does that literature 10 say? What are the potential increased 11 problems? 12 MS. GERSTEL: Object to form. 13 A. The TVT-O has a higher increase 14 in groin pain, which is usually transient. 15 It has a higher increase in vaginal angle 16 perforations. It has a less incidence in 17 bladder injury and retropubic injuries. 18 Q. Is there a -- are you aware of 19 literature saying that there's a two times 20 greater risk of re-operation with 21 transobturator placement versus 22 retropubic? 23 MS. GERSTEL: Object to form. 24 A. You know, the articles that</p> | <p style="text-align: right;">Page 61</p> <p>1 list? 2 MS. GERSTEL: Object to form. 3 A. I'm trying to think if I have 4 some. Let me just check. 5 (Pause.) 6 There are a number on the 7 reliance list, yes. 8 Q. The internal e-mails we just 9 talked about discussed within -- with 10 Ethicon employees discussing laser-cut 11 mesh and the transobturator approach, 12 those are included on your reliance list? 13 A. I'm not aware of that. No, I 14 don't think so. 15 Q. Did you see those documents for 16 the first time in preparation for this 17 deposition? 18 A. I don't -- I think I may have 19 seen them prior to the TVT Retropubic 20 deposition. 21 MS. GERSTEL: Dave, could I 22 state for the record that as the 23 reliance list was prepared by counsel, 24 I believe those e-mails are on Dr.</p> |

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| <p style="text-align: right;">Page 62</p> <p>1 Lind's reliance list.</p> <p>2 MR. DeGREEFF: I think you can</p> <p>3 probably take him through that stuff,</p> <p>4 if you want.</p> <p>5 And you're welcome to state</p> <p>6 whatever you want for the record,</p> <p>7 obviously. But I'm interested in what</p> <p>8 he knows.</p> <p>9 MS. GERSTEL: Okay. I just</p> <p>10 wanted to make clear that the company</p> <p>11 documents that were provided to Dr.</p> <p>12 Lind were put on his reliance list.</p> <p>13 MR. DeGREEFF: Gotcha.</p> <p>14 BY MR. DeGREEFF:</p> <p>15 Q. So, the first time you looked at</p> <p>16 the e-mails we're discussing now was in</p> <p>17 preparation for your prior deposition on</p> <p>18 the TVT and the Gynecare?</p> <p>19 A. Yes.</p> <p>20 Q. So the first time you saw those</p> <p>21 was after you had already rendered your</p> <p>22 opinions?</p> <p>23 A. I don't recall if it was before</p> <p>24 or after.</p> | <p style="text-align: right;">Page 64</p> <p>1 Q. When did you review it?</p> <p>2 A. Three weeks ago.</p> <p>3 Q. And you don't remember who the</p> <p>4 person being deposed in that deposition</p> <p>5 was?</p> <p>6 A. I don't.</p> <p>7 Q. What about the TVT products were</p> <p>8 you interested in from that deposition?</p> <p>9 A. I was interested in knowing what</p> <p>10 another expert did in discussing the</p> <p>11 products. I was interested in what</p> <p>12 counsel was interested in focusing on.</p> <p>13 Q. So, was it another deposition</p> <p>14 taken by my firm?</p> <p>15 A. I believe it was.</p> <p>16 Q. Do you know who took the</p> <p>17 deposition?</p> <p>18 A. Yes. It was Jeff Kuntz.</p> <p>19 Q. Jeff Kuntz (different</p> <p>20 pronunciation)?</p> <p>21 A. Kuntz.</p> <p>22 I'm sorry if I mispronounced it.</p> <p>23 Q. What in particular was it --</p> <p>24 MR. DeGREEFF: Strike that.</p> |
| <p style="text-align: right;">Page 63</p> <p>1 Q. Do you recall seeing them before</p> <p>2 you gave your opinions?</p> <p>3 A. I don't recall.</p> <p>4 Q. Something you considered when</p> <p>5 you were giving your opinions?</p> <p>6 MS. GERSTEL: Object to form.</p> <p>7 A. If I had read them, then I</p> <p>8 considered it. And if I didn't, then I</p> <p>9 didn't. And I don't remember if I saw</p> <p>10 them before or after.</p> <p>11 Q. You said you also reviewed some</p> <p>12 depositions in preparation for this</p> <p>13 deposition.</p> <p>14 Do you remember what depositions</p> <p>15 you reviewed?</p> <p>16 A. I don't remember specifically</p> <p>17 which one it was.</p> <p>18 Q. Do you remember the subject</p> <p>19 matter?</p> <p>20 A. I just asked to see a deposition</p> <p>21 that was on the multiple TVT products.</p> <p>22 Q. Did you review that deposition</p> <p>23 in preparation for today?</p> <p>24 A. Yes.</p> | <p style="text-align: right;">Page 65</p> <p>1 Q. Why did you need to see how</p> <p>2 another expert --</p> <p>3 MR. DeGREEFF: Strike that.</p> <p>4 Q. Was it a plaintiff's expert or a</p> <p>5 defense expert?</p> <p>6 I assume it was a defense expert</p> <p>7 since we were taking it.</p> <p>8 A. Yes.</p> <p>9 Q. Why did you need to see how</p> <p>10 another Ethicon expert responded to the</p> <p>11 questions they were being asked?</p> <p>12 MS. GERSTEL: Object to the</p> <p>13 form.</p> <p>14 A. It's someone going through what</p> <p>15 I was going to go through. It seemed like</p> <p>16 a reasonable review method to hear what</p> <p>17 counsel had to say and take a look at what</p> <p>18 counsel had to say and see if I agreed</p> <p>19 with what the other person said, if I</p> <p>20 would have answered it differently.</p> <p>21 Q. I mean, isn't the most important</p> <p>22 thing just for you to answer the questions</p> <p>23 honestly?</p> <p>24 MS. GERSTEL: Object to form.</p> |

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| <p style="text-align: right;">Page 66</p> <p>1 A. Well, I think the importance is 2 for me to get prepared in the best way I 3 can to have the knowledge and at the same 4 time answer honestly. 5 Q. So, the best way for you to get 6 prepared to have the knowledge for this 7 deposition was to read what another 8 Ethicon defense expert who was being paid 9 by Ethicon said in his deposition or her 10 deposition? 11 MS. GERSTEL: Object to the 12 form. 13 A. The best preparation was review 14 of the literature, which constituted 99 15 percent of my time spent. So this was a 16 small element. 17 Q. Is this the only deposition you 18 reviewed in getting ready for your depo? 19 A. Yes. 20 Q. What about expert reports, did 21 you review any expert reports in preparing 22 for your depo? 23 A. I did not. 24 Q. Before we move on, let me ask</p> | <p style="text-align: right;">Page 68</p> <p>1 got everything that they had or whether 2 some of it was extracted. 3 Q. But the documents you were 4 provided by defense counsel to review were 5 incomplete and did not contain the rest of 6 the thread. 7 True? 8 MS. GERSTEL: Objection. 9 A. Some of them did and some of 10 them did not. 11 MS. GERSTEL: Would it be a good 12 time for a break? Or in the next few 13 minutes. 14 MR. DeGREEFF: Sure. This 15 works. Whatever. 16 (Recess taken.) 17 (Lind Exhibit 6, Curriculum 18 Vitae of Dr. Lind, was marked for 19 identification, as of this date.) 20 BY MR. DeGREEFF: 21 Q. I've just handed you what I've 22 marked as Deposition Exhibit Number 6. 23 Do you recognize that as your 24 current CV?</p> |
| <p style="text-align: right;">Page 67</p> <p>1 this question. 2 With regard to the e-mails that 3 we discussed where the Ethicon employees 4 were discussing outcomes related to 5 laser-cut mesh. 6 Do you agree or disagree with 7 those employees? 8 MS. GERSTEL: Object to form. 9 A. I don't know the full context of 10 where the e-mails were, and I don't know 11 if they were in the middle of discussions 12 of positives or negatives 'cause they're 13 single pages. So I really can't comment 14 on them. 15 Q. So you weren't shown the full 16 document? 17 MS. GERSTEL: Object to form. 18 A. I wasn't shown the full thread 19 of e-mails. They were just extracted 20 pages. 21 Q. Who extracted the pages? 22 MS. GERSTEL: Object to form. 23 A. I don't know what was available 24 to Ethicon and to counsel and whether I</p> | <p style="text-align: right;">Page 69</p> <p>1 A. Yes. 2 Q. Sir, what kind of doctor are 3 you? 4 A. I'm an obstetrician gynecologist 5 with fellowship training in female pelvic 6 medicine and reconstructive surgery. 7 Q. Do you have any board 8 certifications? 9 A. I'm board certified in OB-GYN 10 and I'm subspecialty certified in female 11 pelvic medicine and reconstructive 12 surgery. 13 Q. What states are you licensed to 14 practice medicine in? 15 A. Just New York. 16 Q. Sir, if you look at there's a 17 portion that says "Teaching Experience"? 18 A. Yes. 19 Q. In the teaching experience 20 section of your CV, are any of the things 21 listed there done on behalf of Ethicon? 22 A. The last one, the 2006 to 23 present, the bio skills training labs, we 24 set those up to teach our fellows, and</p> |

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| <p style="text-align: right;">Page 70</p> <p>1 there's usually an educational grant 2 offered by each of the major companies 3 that supply pelvic floor products that 4 usually pick up the cost for the lab. So 5 some of those are supported. They 6 probably would have been between 2006 and 7 2010, some labs that were supported by 8 Ethicon. 9 The rest of them are mostly 10 academic courses that were at a facility 11 and supported by the facility. 12 Q. Okay. 13 So, would Ethicon have -- when 14 you say "supported," you mean paid for. 15 Right? 16 A. They cover the cost of the lab, 17 the cadaver lab for the day. We would not 18 be getting paid for that lab, but they're 19 picking up the expense of cost to use 20 cadavers to teach. 21 Q. What is the cost to use cadavers 22 to teach? 23 A. A lab could be \$30,000. 24 Q. Each lab?</p> | <p style="text-align: right;">Page 72</p> <p>1 Q. -- based on what we just talked 2 about. 3 Is that correct? 4 A. Yes. 5 But I would like to specify that 6 it was the hospital rules and compliance 7 that they would have to have absolutely no 8 input as to the material, slides, things 9 taught, and the products are not 10 exclusively theirs. They were everything 11 that we think the students and fellows 12 need to learn. 13 MR. DeGREEFF: I'm going to move 14 to strike that, and I'm going to ask 15 my question again. 16 My question was pretty simple. 17 It was just a yes or no. 18 Q. Ethicon would have spent 120 to 19 \$180,000 on cadaver labs, based on our 20 discussion? 21 True? 22 MS. GERSTEL: Object to form. 23 A. Across those several years, yes. 24 Q. There's also a list of lectures.</p> |
| <p style="text-align: right;">Page 71</p> <p>1 A. Yeah. The cost for the cadavers 2 and the people who prepare them, maintain 3 them and dispose of them is very high. 4 Q. And Ethicon would pick up one of 5 the -- 6 MR. DeGREEFF: Strike that. 7 Q. How many of those cadaver labs 8 per year would Ethicon pick up? 9 MS. GERSTEL: Objection. 10 A. They probably do one a year in 11 the general teaching sense. 12 Q. For four years or so, is what 13 you're saying? 14 I guess how many years did they 15 do that? 16 A. Yeah, four to six years. 17 And the other companies would do 18 the same. We have a lot of teaching labs. 19 So Boston Scientific would pick up a lab. 20 Caldera would pick up a lab. 21 Q. Okay. 22 So, I mean, Ethicon would have 23 spent 120 to \$180,000 on cadaver labs -- 24 A. Yeah.</p> | <p style="text-align: right;">Page 73</p> <p>1 I guess the title is "Lecture 2 Presentations," on your CV. 3 Do you see that? 4 A. Yes. 5 MR. DeGREEFF: Strike that. 6 Before I do that, let me go back. 7 Q. Who was teaching these cadaver 8 labs that were funded by Ethicon? 9 A. My division, which would be 10 myself and my partners. 11 Q. Would Ethicon fund these cadaver 12 labs at the request of you and your 13 department? 14 A. Yes. 15 Q. Now are the lecture presentation 16 section of your CV. 17 Do you see where I'm at? 18 A. Yes. 19 Q. Were some of those lectures done 20 on behalf of Ethicon? 21 A. The ones listed here are all 22 invited lectures in academic only 23 situations and not for Ethicon. 24 I don't have listed here invited</p> |

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| <p style="text-align: right;">Page 74</p> <p>1 Ethicon lab experiences where I taught at 2 their Ethicon teaching experiences. 3 Q. Does the lecture presentation 4 section include lectures given on behalf 5 of any transvaginal mesh manufacturer? 6 A. No. 7 Q. Why did you not include in your 8 lecture presentation section those that 9 were done on behalf of transvaginal mesh 10 manufacturers? 11 A. I guess when I'm writing an 12 academic CV, I'm thinking about my 13 academic presentations. And those were in 14 a consultant role, so I didn't include 15 them. 16 Q. What is the difference between 17 the lectures you gave in a consulting role 18 versus those given in an academic setting. 19 A. These were advised by me or 20 offered to institutions for teaching 21 purposes only or invited because of my 22 expertise to give teaching, and the others 23 were labs we set up to teach, for which we 24 couldn't have the setting of fresh</p> | <p style="text-align: right;">Page 76</p> <p>1 products, there is not any selection for 2 that lab when Ethicon's paid for it that 3 discusses theirs only. It's we describe 4 everything we use for the reasons we use 5 them. So we presented it in a non-biased 6 way. 7 Q. What you just gave the 8 explanation about, that's what you're 9 referring to in the academic setting. 10 Right? 11 A. The academic setting in my lab. 12 Now, the distinction that will also put it 13 into a teaching category is when Ethicon 14 wanted to teach the procedures, each of 15 these slings or the mesh procedures and 16 they wanted expert surgeons to help train 17 people on fresh cadavers. That would be a 18 different teaching setting which I would 19 say is teaching-slash-consulting. 20 Q. Right. 21 When you're giving lectures as a 22 consultant, you're being paid by Ethicon 23 pursuant to the consulting agreements you 24 signed with them.</p> |
| <p style="text-align: right;">Page 75</p> <p>1 cadavers without the backing of companies 2 because we didn't have the money for the 3 labs. 4 And it was a unique teaching 5 situation. It was really access to the 6 cadavers was the key teaching element. So 7 it was more of a -- it was less of a 8 lecture than the opportunity to execute 9 procedures in a unique way that had really 10 not been done before to be able to do them 11 on fresh cadavers. 12 Q. Well, when you're giving 13 lectures as a consultant for Ethicon, you 14 were being paid. 15 Right? 16 A. Well, let me make a distinction. 17 The labs that we're talking 18 about where I'm teaching at my lab center, 19 I'm lecturing on whatever I want for 20 pelvic reconstructive surgery on various 21 procedures. Some of the procedures have 22 nothing to do with mesh or any product and 23 others do. 24 And in the discussions of mesh</p> | <p style="text-align: right;">Page 77</p> <p>1 Right? 2 A. Yes. 3 Q. And they have input into the 4 materials you're using for those lectures. 5 True? 6 A. I did not permit that. 7 Q. Well, contractually under 8 consulting agreement, they have the right 9 to have input into those materials. 10 Correct? 11 MS. GERSTEL: Object to the 12 form. 13 A. They could have input, but I 14 control the slides. 15 I would never accept a company's 16 slide deck, and I never did. 17 Q. Those two things, i.e. being 18 paid and -- being paid by Ethicon and 19 Ethicon's right to review and have input 20 in your materials, those aren't present in 21 the academic setting. 22 Right? 23 A. Correct. 24 Q. You have a bibliography section</p> |

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1 on your CV. I'm sure you're aware of
2 that.
3 Right?
4 A. Yes.
5 Q. Have you published any
6 peer-reviewed articles regarding any of
7 the Ethicon mesh slings?
8 A. No.
9 Q. Have you published any
10 peer-reviewed articles concerning mesh
11 slings regardless of the manufacturer?
12 A. We contributed cases to a Solyx
13 study, which was published.
14 Q. Was it peer-reviewed?
15 A. Yes.
16 Q. And were you the author, or did
17 you just contribute in some other way to
18 that?
19 A. I was a co-author. I was not
20 the lead author.
21 Q. And which one was the -- on your
22 bibliography was that particular article?
23 A. On the second page, it says
24 Nosseir S, Serels and Lind "Safety and

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1 efficacy of the Solyx single-incision
2 sling."
3 And then we had another -- we
4 had a poster presentation, which is
5 peer-reviewed for acceptance as a poster,
6 but it's not a -- published in a journal a
7 little further down by the same group.
8 Q. And those were both with regard
9 to the Solyx?
10 A. Yes.
11 Q. Any others? Any other
12 peer-reviewed articles related to mesh
13 slings that you published?
14 A. We did on the third page. You
15 can see the first name Shalom where it
16 says "Visualization of synthetic mesh
17 utilizing optical coherence tomography."
18 That wasn't efficacy or complications of
19 mesh, but it was -- what we thought we
20 were trying to do there was, you know,
21 special optical tomography device that
22 would let us find the sling and we thought
23 it might be useful for it when you have to
24 go back and note a little more precisely

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1 where the sling is.
2 Q. So that would be useful for when
3 people were having complications and you
4 needed to look at the sling?
5 A. Yes.
6 Q. Were these two Boston Scientific
7 articles that you discussed that were
8 peer-reviewed, were they funded by Boston
9 Scientific?
10 A. They were.
11 Q. They were?
12 A. Yes.
13 Q. Do you remember how much you
14 were paid for your work on those?
15 A. I do not, but I do -- I can
16 clarify that the funds would go to a
17 research fund and in no way would
18 remunerate me financially.
19 Q. Was there any other of your
20 articles in your bibliography that were
21 funded by transvaginal mesh manufacturers?
22 A. On the second page it has
23 Chohan and Lind, the "Prepubic Approach
24 to Mid-Urethral Slings." That was funded

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1 by Boston Scientific.
2 Q. Okay.
3 A. I'm scanning the rest of them.
4 (Pause.)
5 No others.
6 Q. On the articles that you worked
7 on that were funded by transvaginal mesh
8 companies, did you do a disclosure of
9 conflict of interest?
10 A. Yes.
11 Q. What is the purpose of
12 disclosing that an article was funded by a
13 mesh manufacturer?
14 A. Well, both at the point of
15 patient consent and at the point of
16 publication, the disclosure allows the
17 readers to understand that there was a
18 financial support by a company that has
19 relevance for the result of the study. A
20 reader can decide whether that financial
21 disclosure introduces bias and judge that
22 as to whether or not to credit the study
23 more or less based on that.
24 Q. When someone receives funding or

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| <p style="text-align: right;">Page 82</p> <p>1 payment from an entity, there's potential 2 bias that can result. 3 True? 4 A. There's the potential, yes. 5 Q. How do you define bias? 6 A. Bias is when a -- in the setting 7 of a study, when you're interpreting a 8 study or how you're handling your patients 9 or how you're looking at results, you have 10 a feeling or an impetus to want it to go 11 in one direction or another that may not 12 be objective. That's if you're not 13 handling it properly. 14 So, if you had bias and you were 15 not able to resist bias in a study, you 16 would be influencing the study in one way 17 or another because there was financial 18 support. 19 Q. I think you put it very well in 20 another deposition I saw that you gave. 21 Bias is -- would you agree that 22 bias is anything that affects the 23 objectivity of the outcome of a study? 24 A. Sure. That's one way of looking</p> | <p style="text-align: right;">Page 84</p> <p>1 to how TVT fits into the incontinence 2 surgery products history. 3 I have a number of mesh studies 4 which are relevant to procedures with 5 mesh, whether they're prolapse procedures 6 or incontinence. 7 Q. Well, the TVT products are not 8 for prolapse. 9 Correct? 10 A. Correct. I was indicating that 11 the behavior of the same type of mesh 12 would be relevant to, in a broader scope, 13 how mesh behaves. 14 Q. I think you answered this, but 15 let me just confirm because you said it in 16 a better way than I did. 17 None of the articles included on 18 the bibliography are on the TVT -- any of 19 the TVT sling products. 20 Correct? 21 A. Correct. 22 Q. So you have not been direct -- 23 you have not been involved directly in a 24 published study of any kind related to</p> |
| <p style="text-align: right;">Page 83</p> <p>1 at it. 2 Q. One of the things that could 3 affect the objectivity of a study is 4 funding or payment. 5 True? 6 A. It could, but there are defenses 7 against that. 8 Q. Which, if any, of the articles 9 on your bibliography are relevant to the 10 TVT sling products? 11 MS. GERSTEL: Object to form. 12 A. Well, I think I've got a lot 13 of -- 14 MR. DeGREEFF: Strike that. 15 Let me ask that in a more fair 16 way. That was a pretty broad 17 question. 18 Q. Do any of the articles in your 19 bibliography relate to or address any of 20 the TVT products? 21 A. I think they're not directly 22 studies on TVT products, but I think 23 they're products on -- they're studies on 24 incontinence procedures which are relevant</p> | <p style="text-align: right;">Page 85</p> <p>1 the, or about the TVT products? 2 A. Correct. 3 Q. What are some alternatives to 4 slings? 5 MS. GERSTEL: Object to form. 6 A. There are, historically, there 7 are dozens and dozens of stress 8 incontinence procedures. They include 9 Burch, needle procedure, Pereyra, Stamey, 10 pubovaginal slings, amongst others. 11 Q. Which of the native sling -- 12 MR. DeGREEFF: Strike that. 13 Q. Which of the alternatives to 14 mesh slings are still in use today? 15 A. The pubovaginal slings are still 16 in use. The Burch is still in use, but to 17 a much lesser degree, markedly lesser 18 degree than previously. 19 Q. Biologic slings? 20 A. They are used by a small number 21 of users. They're certainly not a 22 dominant. 23 But in answer to your strict 24 question, yes, those are still in use.</p> |

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| <p style="text-align: right;">Page 86</p> <p>1 Q. And those alternatives are used 2 for the same indications as the TVT mesh 3 slings. 4 True? 5 A. Yes. 6 Q. Have you ever performed the 7 Burch procedure? 8 A. Many, many times. 9 Q. Do you still perform it? 10 A. Yes. 11 Q. How many times have you 12 performed it? 13 A. In my career, 300, 400. 14 Q. When was the last time you did 15 one? 16 A. Within the last few months. 17 Q. How many have you done this 18 year? Any idea? 19 A. Three or four. 20 Q. What about have you ever done 21 the native tissue sling procedure? 22 A. Yes. 23 Q. Do you still do it? 24 A. I do.</p> | <p style="text-align: right;">Page 88</p> <p>1 have some rabbits being implanted with 2 absorb -- partially absorbable and 3 absorbable mesh to analyze the biochemical 4 and histochemical changes during 5 implantation. 6 Q. Are you involved in that at all? 7 A. I'm involved in the chat in our 8 research sessions. They're not my 9 project. I'm not the mentor or co-author 10 on them. But since it's in the division, 11 every Friday we go over products. So I'm 12 privy to the updates and the ongoing 13 happenings on it, but I have no ownership 14 on that project. 15 Q. So you're not -- you've had some 16 conversations about the project, but 17 you're not involved in actually 18 administering the project. 19 Fair? 20 A. Correct. 21 Q. Is that project being funded by 22 a pharmaceutical company -- or, excuse me. 23 A medical device company? 24 A. It is. It's being funded by a</p> |
| <p style="text-align: right;">Page 87</p> <p>1 Q. How many have you done? 2 A. I did two this year. 3 Q. How many have you done in your 4 career? 5 A. 50 to 60. 6 Q. What about the biologic slings, 7 have you ever used one of those? 8 A. I did not. 9 Q. The Burch procedure and the 10 native tissue repair are still viable 11 alternatives to the TVT mesh slings that 12 are still being used. 13 Right? 14 MS. GERSTEL: Object to form. 15 A. Can you just restate that? 16 Q. The Burch and native tissue 17 slings are still available alternatives 18 that are still in use to the TVT slings. 19 Fair? 20 A. Yes. 21 Q. Sir, are you involved in any 22 current research on polypropylene meshes? 23 A. We have a -- I'm not a co-author 24 on it, but we have in our division, we</p> | <p style="text-align: right;">Page 89</p> <p>1 mesh company. 2 Q. Which one? 3 A. I don't know the name. 4 Again, I'm kind of peripheral on 5 this one. 6 Q. Okay. 7 Is it Ethicon? 8 A. It's small. It's not one of the 9 well-known companies. 10 Q. Have you ever written a 11 peer-reviewed journal article on 12 polypropylene mesh? 13 A. Yes. I have a publication on 14 the reduction of the analysis of mesh 15 complications with abdominal sacral 16 suspension done in different ways for 17 abdominal sacral suspension analyzing 18 erosion rates. 19 Q. What product was at issue? 20 A. Gynemesh. 21 Q. Not the TVT products? 22 A. No. 23 Q. Have you ever written on the 24 Burch procedure?</p> |

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| <p style="text-align: right;">Page 90</p> <p>1 A. Yes. I have a couple of 2 publications in my CV. 3 Q. Were those peer-reviewed? 4 A. Yes. 5 Q. What was it, do you remember the 6 subject matters you were writing about? 7 A. The Burch procedure requires a 8 fairly good size incision, and I was 9 instrumental in designing a device that 10 would allow suturing in a very small 11 space. So once the device was approved, I 12 wrote a paper on about 90 patients to see 13 whether a Burch could be achieved in a 14 much smaller incision because with the use 15 of the suturing device, it would 16 facilitate the suturing without needing as 17 much space for visualization. So the goal 18 was to see if I could take a Burch and 19 make it less invasive with an incision 20 that was less than half the size. 21 Q. And what were the results? 22 A. They were excellent. We 23 achieved it. 24 Q. So you came up with a way to</p> | <p style="text-align: right;">Page 92</p> <p>1 them and they patented it, and I did a lot 2 of -- most of the studies to show how it 3 would work and the efficacy and safety. 4 And I wish I had a part 5 ownership because they sold it to Boston 6 Scientific for a nice penny. 7 Q. So, is that device currently in 8 use today? 9 A. Yes, it is. 10 Q. And when did that device get 11 developed? 12 A. I was working on it from '94 to 13 '96, and I think it got sold to Boston 14 Scientific in '96. 15 Q. And the end result was that the 16 Burch procedure, which was an alternative 17 to the TVT mesh slings, became less 18 invasive. 19 True? 20 A. That, as well as a few vaginal 21 procedures that we also had trouble 22 suturing with. It had more than one 23 application in addition to the Burch. 24 Q. Were all three of those articles</p> |
| <p style="text-align: right;">Page 91</p> <p>1 make the Burch a less invasive procedure? 2 A. Yes. 3 Q. Do you have a patent on that 4 product? 5 A. I do not. 6 Q. It feels like there's more to 7 that story. 8 Does someone have a patent on 9 it? 10 A. I -- the rules for -- someone 11 has a patent on it, and I was offered part 12 ownership to it. My academic affiliation 13 and the roles for ownership of 14 intellectual property were such that 15 taking the intellectual property would be 16 a poor financial decision. 17 Q. Gotcha. 18 A. So I just came on as a 19 consultant and continued to help them 20 develop the device. 21 Q. Which medical device company was 22 developing it? 23 A. It was the Laurus Corporation, 24 L-A-U-R-U-S. And we developed it with</p> | <p style="text-align: right;">Page 93</p> <p>1 related to that same issue? 2 A. I think there were two on the 3 in-line suturing device. Yes, they were 4 on the issue of -- did I do sacrospinous? 5 I think one might have been 6 Burch and one might have been sacrospinous 7 suspension. I can check on that, if it 8 matters. 9 Q. Yes. I think you said three. 10 That's why I was asking. 11 (Pause.) 12 A. There's two. One looked at it 13 for the use in sacrospinous suspension. 14 The other one looked at it for the use in 15 Burch. 16 Q. Okay. 17 And what were the findings on 18 the sacrospinous suspension? 19 A. The procedure was able to be 20 performed with less dissection and in less 21 operative time with good efficacy and 22 minimal to no complications. So it didn't 23 add any adverse effects, and it lessened 24 the dissection and operative time.</p> |

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| <p style="text-align: right;">Page 94</p> <p>1 Q. And is that also a -- is that 2 procedure also a sling alternative? 3 A. No. That's for pelvic prolapse. 4 That's for vaginal apex prolapse. 5 Q. Have you ever written anything 6 on the biologic tissue slings? 7 A. I have not. 8 Q. Do you consider yourself an 9 expert on chemical engineering? 10 A. As it relates to slings, yes. 11 Q. And what is the basis? Why are 12 you an expert in chemical engineering? 13 A. Because the issues related to 14 chemical engineering as it pertains to 15 tissue interaction with mesh and implants 16 has been part of my career studying, 17 implanting, taking care of patients, 18 insuring their safety and observing the 19 behavior. So that's 25 years of 20 experience. 21 Q. Do you have any education in 22 chemical engineering? 23 A. I read quite a bit of literature 24 on the behavior of the mesh and how it</p> | <p style="text-align: right;">Page 96</p> <p>1 get made and the width of the fibrils. So 2 I've done reading on how they take it from 3 powder and resin and transformed into 4 materials and the reasons why they make 5 decisions. 6 Q. So, is it your testimony that 7 reading articles about how they make 8 transvaginal -- excuse me. Polypropylene 9 mesh is why you consider yourself a 10 chemical engineering expert? 11 A. Reading articles, seeing the 12 different outcomes of how the chemical 13 engineering goes into making products 14 different and seeing how it behaves in 15 patients and seeing the outcomes for 25 16 years is my basis for stating I'm an 17 expert on that topic as it relates to mesh 18 in sling behavior. 19 Q. And you've seen all of that in 20 your role as a physician. 21 True? 22 A. Yes. 23 Q. No one's ever hired you to be a 24 chemical engineering expert.</p> |
| <p style="text-align: right;">Page 95</p> <p>1 interacts with tissue. So my education is 2 based on independent review of the 3 literature. 4 And I do not have a Ph.D. 5 Q. Well, I think we're talking 6 about two different things. 7 Are you talking about 8 biomaterials right now versus chemical 9 engineering? True? 10 A. Whether it's chemical 11 engineering or biomaterials, how they 12 relate to the behavior of slings implanted 13 in patients, I consider myself an expert. 14 Q. You don't know anything about 15 the chemical engineering of polypropylene 16 mesh itself. 17 True? 18 A. I would say that's false. 19 Q. Okay. Why is it false? 20 A. Because I've read articles about 21 the process of it coming from resin, how 22 it gets transformed from resin, and how it 23 gets made into fibrils and how it gets 24 made into the decision to how the fibrils</p> | <p style="text-align: right;">Page 97</p> <p>1 Right? 2 A. No. 3 Q. No one's ever hired you as a 4 chemical engineer. 5 Right? 6 A. Correct. 7 Q. When you hang your degree on the 8 wall, it doesn't say chemical engineer. 9 Right? 10 A. It does not. 11 Q. Do you consider yourself an 12 expert in pathology? 13 A. As it relates to the behavior of 14 sling and mesh implanted in patients, yes. 15 Q. In your daily practice, what is 16 it that makes you a pathology expert? 17 A. The rabbit studies that we're 18 doing produce pathology slides which we 19 examine for various histochemical 20 properties, tensile strength and 21 mechanical properties, and this is a 22 routine part of the research that our 23 group does. 24 Q. You mean the rabbit studies that</p> |

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| <p style="text-align: right;">Page 98</p> <p>1 the other people in your group are doing. 2 Is that what we're talking 3 about? 4 A. To distinguish though what the 5 other people are doing is I play a role in 6 responding and advising what would be 7 studied, how they're doing the study, 8 response on whether how they're getting 9 the information is correct, whether the 10 staining processes are correct. So I'm 11 involved in the study more than just 12 listening. 13 Q. You're not an author on that 14 study. 15 Right? 16 A. I am not. 17 Q. You are not a co-author on that 18 study. 19 Right? 20 A. I'm an advisor on that study, 21 and I'm part of the education discussions 22 on the process. 23 Q. You are not administering the 24 study.</p> | <p style="text-align: right;">Page 100</p> <p>1 pathologic specimens of mesh and sling 2 material. 3 Q. Do you actually read the 4 histopathologic slides? 5 A. In the studies that we do, I 6 look at the pictures along with our study 7 group, yes. 8 Q. You're talking about the rabbit 9 thing again. 10 Right? 11 A. Yes. 12 Q. Do you actually review 13 histopathologic slides out of humans as 14 part of your practice? 15 A. I do not. 16 Q. You just read the reports that 17 come to you from the pathologists. 18 Right? 19 A. Correct. 20 Q. Have you read any pathology 21 reports related to excised mesh? 22 A. I think the Clave study is one 23 of the studies that gets into that. 24 Q. I mean in your daily practice.</p> |
| <p style="text-align: right;">Page 99</p> <p>1 Right? 2 A. No. 3 Q. I'm correct you're not 4 administering the study. 5 Right? 6 A. Correct. 7 Q. You don't even know who the 8 pharmaceutical company is that's funding 9 the study. 10 Fair? 11 A. That's correct. 12 MS. GERSTEL: Object to form. 13 BY MR. DeGREEFF: 14 Q. Other than that, the rabbit 15 studies, what qualifies you as an expert 16 in pathology based on your daily practice? 17 A. When I review the literature, 18 I'm aware of many articles about excision 19 of specimens, what they look like, how 20 people's opinions and how the pathology's 21 been studied on excised specimens, is 22 there inflammation, is there ingrowth, is 23 there degradation. So I'm very 24 well-versed on the literature related to</p> | <p style="text-align: right;">Page 101</p> <p>1 Have you reviewed reports, 2 pathology reports from the pathologists, 3 related to mesh that was removed from -- 4 A. Yes. 5 Q. -- patients? 6 A. Yes. 7 Q. When you review those reports, 8 do they discuss inflammation of the 9 tissue? 10 A. Sometimes inflammation is 11 mentioned, yes. 12 Q. Do they discuss scar plating 13 related to the mesh? 14 A. I have not read that on a 15 pathology report. 16 Q. Do they discuss degradation of 17 the mesh? 18 A. I have not read that on a 19 pathology report. 20 Q. What is the -- inflammation can 21 lead to pain for a woman. 22 True? 23 A. Yes. 24 Q. And it can lead to chronic pain.</p> |

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| <p style="text-align: right;">Page 102</p> <p>1 Right?</p> <p>2 A. It can, yes.</p> <p>3 Q. And mesh leads to tissue --</p> <p>4 MR. DeGREEFF: Excuse me.</p> <p>5 Strike that.</p> <p>6 Q. Mesh can cause tissue</p> <p>7 inflammation.</p> <p>8 True?</p> <p>9 MS. GERSTEL: Object to form.</p> <p>10 A. It -- I would say the mesh</p> <p>11 itself doesn't cause inflammation, but it</p> <p>12 could potentiate inflammation.</p> <p>13 Q. Mesh itself can cause a foreign</p> <p>14 body reaction.</p> <p>15 True?</p> <p>16 A. Yes.</p> <p>17 Q. And that can lead to</p> <p>18 inflammation?</p> <p>19 A. True.</p> <p>20 Q. Do you consider yourself an</p> <p>21 expert in polymer chemistry?</p> <p>22 A. As it relates to mesh and</p> <p>23 slings, yes.</p> <p>24 Q. This is amazing. If you come up</p> | <p style="text-align: right;">Page 104</p> <p>1 aspects of scientific ways that you can</p> <p>2 analyze what happens to mesh. I am</p> <p>3 participating in a lab that implants mesh,</p> <p>4 excises mesh, testing it for tensile</p> <p>5 strength, looking at it under a microscope</p> <p>6 for various inflammation and histochemical</p> <p>7 changes, and I've been studying this and</p> <p>8 been participating in educational and</p> <p>9 clinical and pathology education for 25</p> <p>10 years.</p> <p>11 Q. That all makes you a doctor,</p> <p>12 right?</p> <p>13 A. No. I'm stating that that makes</p> <p>14 me an expert.</p> <p>15 Q. What is your degree in?</p> <p>16 A. I have an MD.</p> <p>17 Q. Okay.</p> <p>18 What is your undergraduate</p> <p>19 degree in?</p> <p>20 A. I have a bachelor of arts.</p> <p>21 Q. Do you have any educational</p> <p>22 training related to chemistry or</p> <p>23 engineering?</p> <p>24 A. I have 25 years of additional</p> |
| <p style="text-align: right;">Page 103</p> <p>1 with a yes for that, we're -- okay.</p> <p>2 What is your background in</p> <p>3 polymer chemistry?</p> <p>4 A. My answers would be the same as</p> <p>5 I replied previously for my background</p> <p>6 for --</p> <p>7 Q. Okay. So, your answer to -- I</p> <p>8 just want to make sure anything I asked</p> <p>9 you about chemistry or chemical</p> <p>10 engineering, your answer is going to be</p> <p>11 I've read articles on polypropylene mesh</p> <p>12 and I listen to updates on the rabbit</p> <p>13 study.</p> <p>14 Right? Those are the two</p> <p>15 things?</p> <p>16 MS. GERSTEL: Object to form.</p> <p>17 A. No. I would expand on that.</p> <p>18 Q. Okay. What else?</p> <p>19 A. For 25 years, I've implanted</p> <p>20 mesh. I've looked at explanted specimens</p> <p>21 and pathology reports. I have studied the</p> <p>22 literature. I've read literature, both</p> <p>23 positive and negative, on various</p> <p>24 engineerings, polymer chemistry and other</p> | <p style="text-align: right;">Page 105</p> <p>1 education as described previously.</p> <p>2 Q. What you described was 25 years</p> <p>3 of being a doctor, right?</p> <p>4 That's what you're relying on</p> <p>5 for being a chemist and an engineer?</p> <p>6 A. That was not my answer.</p> <p>7 MS. GERSTEL: Object to form.</p> <p>8 BY MR. DeGREEFF:</p> <p>9 Q. I'm asking you also consider</p> <p>10 yourself a biomaterials specialist based</p> <p>11 on all the stuff we talked about?</p> <p>12 A. Yes.</p> <p>13 Q. Any other reasons?</p> <p>14 A. I think we've gone through them.</p> <p>15 Q. That's all of them?</p> <p>16 I'm just making sure there's not</p> <p>17 anything else.</p> <p>18 A. On biomaterials I think you</p> <p>19 certainly can say in that area, I have</p> <p>20 published and tested things on my own,</p> <p>21 published them and participated in</p> <p>22 advising and testing in cadaver labs and</p> <p>23 published materials on my own. So my</p> <p>24 additional evidence of expertise is</p> |

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| <p style="text-align: right;">Page 106</p> <p>1 stronger in that area.</p> <p>2 Q. Have you ever published any</p> <p>3 opinions that polypropylene mesh does not</p> <p>4 degrade in the human body?</p> <p>5 MS. GERSTEL: Object to form.</p> <p>6 A. I haven't published it.</p> <p>7 Q. Do you consider yourself an FDA</p> <p>8 expert?</p> <p>9 MS. GERSTEL: Object to form.</p> <p>10 A. I'm distinctly aware of FDA</p> <p>11 matters and paperwork as it relates to</p> <p>12 mesh products and Ethicon mesh products</p> <p>13 and the rules that go into IFUs.</p> <p>14 I would not say I am a</p> <p>15 comprehensive FDA expert.</p> <p>16 But I would say, as it relates</p> <p>17 to the matters in this case, I would say</p> <p>18 I've reviewed the pertinent documents and</p> <p>19 are comfortably familiar with that.</p> <p>20 Q. What are the pertinent</p> <p>21 documents?</p> <p>22 A. There's a Blue Book memo and a</p> <p>23 second FDA document that describes what's</p> <p>24 required in the release of a product, what</p> | <p style="text-align: right;">Page 108</p> <p>1 Q. Was that before or after you</p> <p>2 gave your opinions?</p> <p>3 A. That was before.</p> <p>4 Q. So, what you're claiming makes</p> <p>5 you an expert on the FDA is materials you</p> <p>6 reviewed in preparing for to be a</p> <p>7 litigation expert for Ethicon.</p> <p>8 Is that right?</p> <p>9 A. Well, if someone were to ask me</p> <p>10 if I'm an expert in FDA in the broad sense</p> <p>11 of the word, the general everything that</p> <p>12 they take care of, I would say no.</p> <p>13 If I'd say as it pertains to the</p> <p>14 relevant issues to the materials involved</p> <p>15 in this case, I would say I have very</p> <p>16 thoroughly read through the relevant</p> <p>17 documents and therefore consider myself an</p> <p>18 expert as it relates to mesh products and</p> <p>19 adverse warnings and what needs to be</p> <p>20 included.</p> <p>21 Q. Did you read the 510(k)</p> <p>22 submission for this product?</p> <p>23 A. At some point I did.</p> <p>24 MS. GERSTEL: Object to form.</p> |
| <p style="text-align: right;">Page 107</p> <p>1 has to be on labeling, what has to be</p> <p>2 included in adverse events, and as it</p> <p>3 relates to this particular, you know,</p> <p>4 issue at hand is what adverse events are</p> <p>5 necessary to be included in an IFU.</p> <p>6 Q. Because it sounds like you're</p> <p>7 not claiming you're an FDA expert. You're</p> <p>8 claiming you're an IFU expert.</p> <p>9 Right?</p> <p>10 MS. GERSTEL: Object to form.</p> <p>11 A. I claim to be an FDA expert as</p> <p>12 it relates to adverse reactions and the</p> <p>13 rules necessary and laid out as to what</p> <p>14 needs to be included.</p> <p>15 Q. How did you become aware of --</p> <p>16 MR. DeGREEFF: Strike that.</p> <p>17 Q. Under what circumstances did you</p> <p>18 review these FDA materials related to</p> <p>19 Ethicon products?</p> <p>20 A. Well, in discussing with counsel</p> <p>21 became clear that, you know, what warnings</p> <p>22 are in the IFU is of quick relevant to</p> <p>23 these cases and I said I'd like to see the</p> <p>24 FDA documents that dictate the rules.</p> | <p style="text-align: right;">Page 109</p> <p>1 BY MR. DeGREEFF:</p> <p>2 Q. Did you read all the testing</p> <p>3 submitted with the 510(k)?</p> <p>4 MS. GERSTEL: Objection.</p> <p>5 A. I don't know if I read all of</p> <p>6 the testing. I think I was made familiar</p> <p>7 with some of it.</p> <p>8 Q. Do you know the difference</p> <p>9 between clearance and approval of a</p> <p>10 product?</p> <p>11 A. There are different pathways to</p> <p>12 go through the FDA. There's a 510(k)</p> <p>13 pathway, which is based on a precedent,</p> <p>14 and then there's another pathway where</p> <p>15 based on data, it's you go through based</p> <p>16 on your own merit and data.</p> <p>17 Q. What's the other pathway called?</p> <p>18 A. I don't know.</p> <p>19 Q. Does 510(k) end up with approval</p> <p>20 or clearance in the end?</p> <p>21 A. Approval.</p> <p>22 Q. Would you be surprised to find</p> <p>23 out that 510(k) ends up with clearance?</p> <p>24 A. I'm sorry.</p> |

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| <p style="text-align: right;">Page 110</p> <p>1 Q. Would you be surprised to find 2 out that 510(k) ends up with compliance, 3 not approval? 4 MS. GERSTEL: Object to form. 5 A. I may have that vocabulary 6 confused. 7 Q. As a FDA expert, do you think 8 you should probably know the difference 9 between clearance and approval? 10 MS. GERSTEL: Object to form; 11 argumentative. 12 A. I think the key elements here 13 are what the rules are for what needs to 14 be included in an IFU, and I don't think 15 the rules of what the vocabulary term is 16 for approval versus otherwise is the key 17 element. 18 So no, I wouldn't consider that 19 eliminating myself as an expert to the 20 relevant materials. 21 Q. What I'm taking what you're 22 saying is that you do consider yourself an 23 expert on warnings? 24 A. Yes.</p> | <p style="text-align: right;">Page 112</p> <p>1 guidance number G91-1. So at times I may 2 have to refer, since I haven't memorized 3 everything that exists in all of these 4 binders in my report. 5 Q. You think an FDA expert on 6 warnings would know that? 7 MS. GERSTEL: Object to form; 8 argumentative. 9 A. I think an FDA expert on the 10 entirety of the FDA would know that, but 11 that does not exclude me from being an 12 expert on the areas that I previously 13 described. 14 Q. What departments of a medical 15 device company are involved in creating 16 warnings? 17 A. When I have participated on 18 discussions about what should be included, 19 there's research and development, there 20 was regulatory, and there was compliance. 21 Q. Have you ever read any testimony 22 from Ethicon employees regarding Ethicon's 23 position on what belongs in an IFU? 24 A. I don't recall.</p> |
| <p style="text-align: right;">Page 111</p> <p>1 Q. What risk information are 2 medical device companies required to put 3 in their IFUs? 4 A. They're required to put in the 5 most common and adverse reactions that are 6 unique to the product, and they are not 7 required to put in things that are 8 commonly known. 9 Q. What industry standards govern 10 warnings in medical devices? 11 MS. GERSTEL: Object to form. 12 A. The FDA. 13 Q. What are the various sections of 14 the regulations that relate to warnings 15 for IFUs? 16 MS. GERSTEL: Object to form. 17 BY MR. DeGREEFF: 18 Q. And for the record, you're 19 currently looking to your report to give 20 you that answer. 21 Correct? 22 A. That would be correct, because I 23 can't always memorize that it is 24 21 CFR 801.109(c) and device labeling</p> | <p style="text-align: right;">Page 113</p> <p>1 Q. Have you ever drafted an IFU for 2 a medical device? 3 A. I didn't draft it. 4 I participated in discussions 5 about what should be included and what 6 shouldn't. 7 Q. What was your participation? 8 A. It was in -- with Boston 9 Scientific in releasing a few of their 10 products. 11 Q. Which products? 12 A. It was the Advantage and then it 13 was their Prolene mesh for sacral 14 suspensions. 15 Q. Did they pay you to do that? 16 A. Yes. 17 Q. How much? 18 A. Whatever my hourly was then. It 19 was a little lower, \$300 an hour. 20 Q. How many hours did you spend 21 working on that IFU? 22 A. Probably two expert sessions. I 23 would say twelve. 24 Q. Was that like a roundtable</p> |

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| <p style="text-align: right;">Page 114</p> <p>1 discussion about what kind of warnings 2 should be in the IFU?</p> <p>3 A. Usually was -- it usually was a 4 couple of hours in the lab, then followed 5 up by roundtable discussion.</p> <p>6 Q. Was the purpose of the lab to 7 test out the implant, how it worked with 8 the implant of the device?</p> <p>9 A. Correct.</p> <p>10 Q. And after you made your 11 recommendations, you didn't have any 12 involvement in the actual drafting of the 13 IFU?</p> <p>14 A. I did not.</p> <p>15 Q. Do you agree that physicians 16 should be made aware of the significant 17 safety risks with a product in the IFU?</p> <p>18 MS. GERSTEL: Object to form.</p> <p>19 A. Well, the definition of 20 significant is -- requires a larger 21 discussion than a yes/no question.</p> <p>22 Q. How do you define significant?</p> <p>23 MS. GERSTEL: Object to form.</p> <p>24 A. I would define it as I did</p> | <p style="text-align: right;">Page 116</p> <p>1 required to disclose all significant risks 2 to doctors that come with the use of the 3 device?</p> <p>4 MS. GERSTEL: Object to form.</p> <p>5 A. No.</p> <p>6 Q. You do not agree?</p> <p>7 A. I do not agree.</p> <p>8 Q. Were you ever provided the 9 deposition of Ethicon's medical director 10 Dr. Weissberg?</p> <p>11 A. I don't recall it.</p> <p>12 Q. If the medical director 13 testified that that's the case, do you 14 disagree with Ethicon's medical director?</p> <p>15 MS. GERSTEL: Object to form.</p> <p>16 A. Yes.</p> <p>17 Q. The warnings and adverse 18 reactions section should include all 19 significant risks and complications 20 related to the use of the TVT products. 21 Do you agree?</p> <p>22 MS. GERSTEL: Object to form.</p> <p>23 A. Did your statement say "all"?</p> <p>24 Q. Yes.</p> |
| <p style="text-align: right;">Page 115</p> <p>1 before, where they have to describe the 2 most common and unique adverse reactions 3 to the product, but they don't necessarily 4 have to provide -- list adverse reactions 5 that are commonly known.</p> <p>6 Q. Have you ever read the 7 deposition of Ethicon employee Catherine 8 Beef [ph]?</p> <p>9 A. I have not.</p> <p>10 Q. Is that something that's on your 11 reliance list?</p> <p>12 A. I'm not -- I don't recall seeing 13 that. I don't know if it's on the 14 reliance list.</p> <p>15 Q. If it was her testimony that 16 physicians should be made aware of all 17 significant safety risks associated with a 18 product in the IFU, is that something you 19 disagree with?</p> <p>20 MS. GERSTEL: Object to form.</p> <p>21 A. Yes, I disagree.</p> <p>22 Q. Do you agree that the 23 manufacturer of a medical device that's 24 going to be implanted in a woman's body is</p> | <p style="text-align: right;">Page 117</p> <p>1 A. I disagree.</p> <p>2 Q. Have you ever read the 3 deposition of Ethicon's medical director 4 Dr. Robinson?</p> <p>5 A. No.</p> <p>6 Q. If that was the testimony, do 7 you disagree with it?</p> <p>8 A. I disagree with it.</p> <p>9 Q. Do you agree that doctors rely 10 on medical device companies, such as 11 Ethicon, to tell them whether the products 12 they manufacture are safe?</p> <p>13 MS. GERSTEL: Object to form.</p> <p>14 A. I think the company provides a 15 small piece of a doctor's understanding 16 and learning if something is safe. It's 17 not the major role at all.</p> <p>18 Q. So you believe they rely on them 19 in part for that information?</p> <p>20 A. Correct.</p> <p>21 Q. Do you agree that doctors rely 22 on medical device companies, such as 23 Ethicon, to investigate and test the 24 safety of their products before putting</p> |

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| <p style="text-align: right;">Page 118</p> <p>1 them on the market?</p> <p>2 MS. GERSTEL: Object to form.</p> <p>3 A. I think that they are interested</p> <p>4 in testing prior to release, yes.</p> <p>5 Q. Is that something that you as a</p> <p>6 physician want the medical device</p> <p>7 providers to do?</p> <p>8 A. Yes.</p> <p>9 Q. Do you agree that the company</p> <p>10 knows more about the design features and</p> <p>11 potential risks of their products than</p> <p>12 physicians do?</p> <p>13 MS. GERSTEL: Object to form.</p> <p>14 A. In the early development stage,</p> <p>15 I would agree with you, and then when it's</p> <p>16 out there, I would say there's -- you</p> <p>17 know, the doctors had the ones putting it</p> <p>18 in, seeing how it behaves and seeing the</p> <p>19 patients. So there are -- I think that</p> <p>20 changes. I think it -- I think it changes</p> <p>21 and the doctors can become more expert as</p> <p>22 to efficacy and safety of the device and</p> <p>23 how the features are panning out than the</p> <p>24 companies who make it.</p> | <p style="text-align: right;">Page 120</p> <p>1 A. It's not routinely offered, but</p> <p>2 there are certainly many times where I've</p> <p>3 asked for that type of information and</p> <p>4 it's been disclosed readily.</p> <p>5 Q. But you had to ask for it.</p> <p>6 True?</p> <p>7 A. Yeah. Yes.</p> <p>8 Q. Do you agree that if there's</p> <p>9 reasonable association between a product</p> <p>10 and an adverse event, a company should</p> <p>11 disclose that information?</p> <p>12 MS. GERSTEL: Object to form.</p> <p>13 A. You know, the reasonable</p> <p>14 association specification in your question</p> <p>15 stumps me a little bit because it depends.</p> <p>16 It's really -- there's a continuum of how</p> <p>17 much information they get. And at a</p> <p>18 certain point, if there's a very, very</p> <p>19 strong relationship between a product and</p> <p>20 an adverse event, yes, I think it should</p> <p>21 be disclosed, but there's really a</p> <p>22 continuum between how much they know and</p> <p>23 when that should be shared.</p> <p>24 Q. Okay.</p> |
| <p style="text-align: right;">Page 119</p> <p>1 Q. The physicians are not privy to</p> <p>2 the results of the testing and studies</p> <p>3 that are done by the company prior to</p> <p>4 putting the product on the market.</p> <p>5 True?</p> <p>6 MS. GERSTEL: Object to form.</p> <p>7 A. They're privy to some of them.</p> <p>8 When you have the -- typically the lead</p> <p>9 inventor or authors gather data, they're</p> <p>10 usually privy to that. When a company</p> <p>11 would approach me with a product, first</p> <p>12 thing I'd say is can you show me the data</p> <p>13 you have on it, and they would share that.</p> <p>14 So I am privy to the data they have.</p> <p>15 They typically would not go</p> <p>16 through all of the R&D bench testing, and</p> <p>17 some other items would not be included in</p> <p>18 that.</p> <p>19 Q. Right.</p> <p>20 Doctors would not be privy to</p> <p>21 the bench testing results done by a</p> <p>22 medical device company, such as Ethicon.</p> <p>23 Right?</p> <p>24 MS. GERSTEL: Object to form.</p> | <p style="text-align: right;">Page 121</p> <p>1 So, would you agree that the</p> <p>2 information that a medical device</p> <p>3 manufacture, such as Ethicon, includes in</p> <p>4 its IFUs should not be misleading?</p> <p>5 MS. GERSTEL: Object to form.</p> <p>6 A. I could agree with that.</p> <p>7 Q. Do you agree that the</p> <p>8 information a medical device manufacture</p> <p>9 includes in its IFU should have a</p> <p>10 scientific basis?</p> <p>11 MS. GERSTEL: Object to form.</p> <p>12 A. I think it has a scientific</p> <p>13 basis, as well as a clinical experience</p> <p>14 basis in terms of the things that are</p> <p>15 commonly known.</p> <p>16 Q. So it should be a scientific and</p> <p>17 clinical basis?</p> <p>18 A. I think so, yes.</p> <p>19 Q. And a medical device</p> <p>20 manufacturer should put the safety of its</p> <p>21 patients first.</p> <p>22 True?</p> <p>23 MS. GERSTEL: Object to form.</p> <p>24 A. Yes.</p> |

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| <p style="text-align: right;">Page 122</p> <p>1 Q. Even above profits. 2 Fair? 3 MS. GERSTEL: Object to form. 4 A. Yes. 5 Q. Do you agree that a medical 6 device company, such as Ethicon, is 7 required to make its products reasonably 8 safe? 9 MS. GERSTEL: Object to form. 10 A. Yes. 11 Q. Lastly, do you agree that if a 12 medical device manufacturer sells two 13 products that do the same thing, the 14 medical device manufacturer should stop 15 selling the less safe product and only 16 sell the safer product? 17 MS. GERSTEL: Object to form. 18 A. The evidence and the data 19 distinguishing those adverse events would 20 need to be compared to get to a point 21 where it was convincing that one of them 22 definitively was as efficacious and/or 23 safer. 24 So, it's a -- it depends on the</p> | <p style="text-align: right;">Page 124</p> <p>1 you go the two different routes, and based 2 on patient's anatomy and doctor's 3 backgrounds, they may be safer in 4 different doctors' hands and they also may 5 be safer based on the patient's previous 6 surgery history. 7 Q. So you can't answer my question 8 as asked, is what you're telling me? 9 A. No, I cannot. 10 Q. Have you ever read the 11 deposition of Dr. Holste? 12 A. No. 13 Q. Was that ever provided to you by 14 the defense for review? 15 A. Not that I recall. 16 Q. If that was the testimony, do 17 you disagree? 18 A. Yes. 19 Q. Are you an expert on the design 20 of medical devices? 21 A. I think I am. 22 Q. And what qualifies you as an 23 expert on the design of medical devices? 24 A. Well, I made a really awesome</p> |
| <p style="text-align: right;">Page 123</p> <p>1 level of evidence. 2 Q. Let me ask my question again. 3 Do you agree that if a medical 4 device manufacturer sells two products 5 that do the same thing, that the medical 6 device manufacturer should stop selling 7 the less safe product, assuming it's 8 definitive, and only sell the safer 9 product? 10 MS. GERSTEL: Object to form. 11 A. I can't agree with that because 12 there are situations where something has a 13 higher risk, so let's say for example leg 14 pain with an obturator sling. It's the 15 better choice, even though if you -- just 16 looking at data as a higher risk of thigh 17 pain or leg pain, it's the better choice 18 for a patient because the patient may have 19 retropubic problems or cancer there or 20 radiation there or hernia there. So it 21 now becomes the better choice. So if 22 you're just looking at the data, you'd say 23 well, higher leg pain, maybe we shouldn't 24 use it. But having the two available lets</p> | <p style="text-align: right;">Page 125</p> <p>1 suturing device that allowed people to 2 suture in really small places and made a 3 whole bunch of other people millions of 4 dollars. And it's really cool and it 5 required some really neat engineering. 6 I think I have a unique 7 appreciation for the very significant 8 angles and spaces we're in in pelvic 9 surgery. 10 I think I have an intuitive 11 thought process as to how to think of 12 things that might let us do things more 13 easily. 14 I understand research design and 15 how to test things properly. 16 I think I have shown in my body 17 of work the ability to test meshes and 18 figure out how to decrease erosions, how 19 to suture in small places. And I think 20 I've spent 25 years thinking about the 21 design of instruments and have a pretty 22 good background. 23 Q. Have you ever designed a 24 transvaginal mesh product?</p> |

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| <p style="text-align: right;">Page 126</p> <p>1 A. I've proposed some and some are 2 under consideration, but none are 3 presently being adopted or funded for 4 production. 5 Q. Have you been -- 6 MR. DeGREEFF: Strike that. 7 Q. Have you designed any mesh 8 slings? 9 A. The innovations that I have in 10 mind, which, you know, presently have been 11 proposed to a couple of engineers and to a 12 couple of companies, they have less to do 13 with the sling than with the trocar 14 introduction, and so it's part of the 15 sling system, but it's not the mesh 16 itself. I would say the group that we're 17 working with, of course, my practice, you 18 know, as the role that I play in that 19 process, you know, it's a very close 20 division. I've definitely got my eye on 21 how absorbable meshes are going to behave 22 as we continue to study them. 23 Q. So, what are the changes to the 24 trocar that you've made in these new</p> | <p style="text-align: right;">Page 128</p> <p>1 into this. So it would be their meshes 2 and it would just be changing the trocar 3 insertion. 4 Q. What weight of mesh do Boston 5 Scientific and Caldera use? 6 A. I don't have their mesh weight 7 by memory. They're all type 1 wide pore 8 mesh. 9 Q. Why did you not go to Ethicon 10 for their mesh? 11 A. I've had a closer working 12 relationship with these two companies for 13 the past five, six years. 14 Q. Does the Ethicon product have 15 smaller pore mesh than BSC and Caldera? 16 A. They're pretty close. I think 17 Caldera is less, is smaller. I don't 18 recall where Boston Scientific is related 19 to TVT. 20 Q. Well, Caldera is actually larger 21 pore mesh than the Ethicon product. 22 Correct? 23 A. I'm not sure about that. 24 Q. What about BSC is actually a</p> |
| <p style="text-align: right;">Page 127</p> <p>1 devices that you've designed? 2 A. I'm going to have to say that's 3 confidential. 4 Let me just clarify that to give 5 you something. 6 I think that we -- sometimes 7 when you pass a trocar and you did 8 cystoscopy because you want to see if the 9 pass went into the bladder and sometimes 10 it's missed even though trocar looks 11 pretty big under cystoscopy. So I have a 12 design proposal that would decrease or 13 eliminate the chances of missing a very 14 small passage into the bladder. 15 Q. What weight of mesh do you use 16 in the -- in your new products? 17 A. I haven't gotten to the point of 18 choosing the mesh. I'm only designing the 19 trocar. So the mesh would be -- there's 20 two companies it's proposed to, and the 21 mesh would be whichever company decided to 22 move this forward, I'm comfortable with 23 both of their sling products. So you have 24 both Caldera and Boston Scientific looking</p> | <p style="text-align: right;">Page 129</p> <p>1 larger pore mesh than Ethicon mesh too. 2 Right? 3 MS. GERSTEL: Object to form. 4 A. I don't have those comparisons 5 in my head. 6 What I know is that they're all 7 in the order of ten times wider pores than 8 what is felt to be the minimum necessary 9 for favorable characteristics as described 10 by AMA. 11 Q. Regardless, when you decided you 12 needed mesh for a product you're 13 developing, you sought that mesh from 14 Caldera and Boston Scientific, not from 15 Ethicon. 16 True? 17 A. I wasn't seeking mesh. I was 18 seeking someone who thought an 19 introduction needle had an advantage. 20 Q. Okay. 21 The two companies you went to 22 for your product were Caldera and BSC, not 23 Ethicon. 24 True?</p> |

| Page 130 | Page 132 |
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| <p>1 A. Yes.</p> <p>2 Q. And you could have gone to</p> <p>3 whatever companies you wanted to.</p> <p>4 Right?</p> <p>5 A. Yes.</p> <p>6 Q. And you had a working</p> <p>7 relationship with Ethicon.</p> <p>8 Right?</p> <p>9 A. Yes.</p> <p>10 Q. When was this that you were</p> <p>11 approaching these companies?</p> <p>12 A. In the past two years.</p> <p>13 Q. So you had a relationship with</p> <p>14 the company in Ethicon that has paid you</p> <p>15 200 to \$250,000 as a litigation expert.</p> <p>16 Right?</p> <p>17 MS. GERSTEL: Object to form.</p> <p>18 A. Yes.</p> <p>19 Q. Has Ethicon ever asked you to</p> <p>20 consult on the design of any of their mesh</p> <p>21 products?</p> <p>22 A. I was in a consulting R&D</p> <p>23 session on whether or not to make the</p> <p>24 trocar smaller when they were considering</p> | <p>1 A. I'm not doing it at all.</p> <p>2 Q. You don't have any --</p> <p>3 MR. DeGREEFF: Strike that.</p> <p>4 Q. You don't have any patents on</p> <p>5 medical devices currently.</p> <p>6 True?</p> <p>7 A. Correct.</p> <p>8 Q. Did you have involvement with</p> <p>9 the design of the Solyx, the Boston</p> <p>10 Scientific Solyx?</p> <p>11 A. We may have mentioned this</p> <p>12 before. That was the one time where I</p> <p>13 was -- yes, I was in their R&D labs giving</p> <p>14 them feedback on pre-release research and</p> <p>15 development design phase and a positive</p> <p>16 and negative feedback on it, which was on</p> <p>17 their company documents, which ended up</p> <p>18 with me in a deposition not on either</p> <p>19 side, just called to be deposed on what I</p> <p>20 had written in that R&D lab.</p> <p>21 Q. Are you familiar with the</p> <p>22 industry standards that govern medical</p> <p>23 device design?</p> <p>24 MS. GERSTEL: Object to the</p> |
| Page 131 | Page 133 |
| <p>1 the TVT Exact. So that's not a mesh</p> <p>2 decision, but again part of the mesh</p> <p>3 system. I know they were interested in</p> <p>4 what I thought of the Gynecare mesh just</p> <p>5 because I had used it a lot. So, it</p> <p>6 wasn't -- the Gynemesh had been, you know,</p> <p>7 a smaller cut piece of a previous type of</p> <p>8 mesh they had previously used. So they</p> <p>9 were interested in a lot of my input</p> <p>10 because they know I used it a lot and I</p> <p>11 published on it. So they asked if they</p> <p>12 could do anything different with it, and I</p> <p>13 said my patients are doing extremely well,</p> <p>14 so I'm happy with it.</p> <p>15 Q. Gynecare mesh you were using</p> <p>16 that for pelvic organ prolapse?</p> <p>17 A. Yes. And there was a time when</p> <p>18 I was using it for individually cut sewed</p> <p>19 prolapse vaginal procedures.</p> <p>20 Q. As you sit here today, it's no</p> <p>21 longer possible to use Gynecare for repair</p> <p>22 of pelvic organ prolapse.</p> <p>23 Correct?</p> <p>24 MS. GERSTEL: Object to form.</p> | <p>1 form.</p> <p>2 A. I'm familiar with a number of</p> <p>3 the FDA standards.</p> <p>4 Q. What are those regulatory</p> <p>5 standards?</p> <p>6 A. Well, there's clearances and</p> <p>7 approval processes they have to go</p> <p>8 through. There's device labeling</p> <p>9 instructions.</p> <p>10 Q. Anything else that you can think</p> <p>11 of?</p> <p>12 A. There's classifications that</p> <p>13 tell you how much -- whether something is</p> <p>14 based on something previous, how much data</p> <p>15 needs to come before release.</p> <p>16 Q. Have you reviewed any Ethicon</p> <p>17 internal standards on medical device</p> <p>18 design?</p> <p>19 A. I don't recall.</p> <p>20 Q. Are you familiar with the stage</p> <p>21 gate system?</p> <p>22 A. I am not.</p> <p>23 Q. Do you know what a clinical</p> <p>24 expert report is?</p> |

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| <p style="text-align: right;">Page 134</p> <p>1 A. I think it's a -- it's a 2 detailed statement on where the company 3 feels a product is in terms of its 4 research and development. I'm not certain 5 on that.</p> <p>6 Q. Have you reviewed any of 7 Ethicon's clinical expert reports related 8 to the TVT mesh sling products?</p> <p>9 A. Since the title sounds familiar, 10 I think I read one, and I don't recall 11 which one it was or any of the details, 12 but I think I -- it was in front of me at 13 one point.</p> <p>14 Q. As you sit here, you just don't 15 remember anything about what it said?</p> <p>16 A. No.</p> <p>17 Q. True?</p> <p>18 A. Correct.</p> <p>19 Q. Do you know what a design 20 history file is?</p> <p>21 A. No, but the name kind of gives 22 it away. But the answer to your question 23 would be no.</p> <p>24 Q. Have you ever reviewed the</p> | <p style="text-align: right;">Page 136</p> <p>1 A. Well, the key ones were Olmstead 2 for the TVT and De Lara for the obturator 3 products.</p> <p>4 Q. Have you read those depositions?</p> <p>5 MS. GERSTEL: Object to form.</p> <p>6 A. I have not read their 7 depositions, no.</p> <p>8 Q. Were those depositions given to 9 you by defense counsel?</p> <p>10 MS. GERSTEL: Object to form; 11 lack of foundation.</p> <p>12 A. I don't recall them being given 13 to me.</p> <p>14 Q. What is Med Scan?</p> <p>15 A. Is that the Canada group? No? 16 I don't know what it is.</p> <p>17 Q. What is Provincia?</p> <p>18 A. I don't know.</p> <p>19 Q. Do you know what a design 20 failure modes and effects analysis is?</p> <p>21 A. Say it again. Design failure?</p> <p>22 Q. Modes and effects analysis.</p> <p>23 A. I couldn't describe it to you 24 specifically.</p> |
| <p style="text-align: right;">Page 135</p> <p>1 design history file, Ethicon's design 2 history file, with regard to any of the 3 TVT products?</p> <p>4 A. I can tell you that I've read 5 quite a number of documents that describe 6 the evolution of the TVT products. I 7 don't know if that's within that stated 8 document.</p> <p>9 So, the answer is that document 10 by name I'm not familiar with, but I'm 11 certainly familiar with many documents 12 that describe the evolution of the TVT and 13 the TVT product family.</p> <p>14 Q. What is contained in the design 15 history file?</p> <p>16 A. Since I haven't seen the file, 17 I -- I can't tell you.</p> <p>18 Q. So, as you sit here, is it fair 19 to say you don't know whether you've 20 reviewed the design history file or not?</p> <p>21 A. Correct.</p> <p>22 Q. What employees from Ethicon were 23 involved in the design of the TVT 24 products?</p> | <p style="text-align: right;">Page 137</p> <p>1 Q. Ever participated in one?</p> <p>2 A. Well, if putting something on 3 tension to seeing load failure and various 4 other changes in the characteristics of 5 the mesh when you do different things to 6 it is part of it, then yes.</p> <p>7 Whether I knew that I was 8 specifically in a session that was labeled 9 that, I don't recall that it had that 10 name.</p> <p>11 Q. What are the different types of 12 failure modes and effects analysis?</p> <p>13 A. Can't answer that.</p> <p>14 Q. Just don't know?</p> <p>15 A. Correct.</p> <p>16 Q. Did you review any of the design 17 failure modes effects analysis on the TVT 18 mesh slings?</p> <p>19 A. I may have, but not knowing it 20 had that title.</p> <p>21 Q. As you sit here, you just don't 22 know whether you did or not?</p> <p>23 A. Correct.</p> <p>24 Q. Are you aware of any company</p> |

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| <p style="text-align: right;">Page 138</p> <p>1 other than Ethicon that marketed a -- that 2 marketed mesh that was mechanical-cut? 3 MS. GERSTEL: Object to form. 4 A. Caldera's is mechanically-cut. 5 Q. Which product? 6 A. The Desara and the Desara TV 7 Blue. There may be others, but I know 8 that that one is. 9 Q. Have you ever reviewed any of 10 Ethicon's internal operating procedures 11 related to design? 12 A. I've read a lot of pages that 13 discuss how -- how a procedure is going to 14 be designed. And again, whether it had 15 that title, I don't know. I've recently 16 read a number of Ethicon documents that 17 are discussing the process for design and 18 feasibility and opinions as to where the 19 product stands. 20 Q. So you don't know if you've 21 reviewed the standard operating procedure 22 or not. 23 True? 24 A. Specifically the document by</p> | <p style="text-align: right;">Page 140</p> <p>1 document had to do with a need to -- a 2 wish to get this moving along based on 3 competition. I do remember a document 4 that had that type of theme. 5 Q. Is it your understanding that 6 Ethicon wanted to get the TVT-O to market 7 as quickly as possible? 8 MS. GERSTEL: Object to form. 9 A. The only thing I recall was that 10 there was -- there was wording that 11 expressed a wish for it to be released and 12 the timing of the release was important 13 based on competition. 14 Q. So they wanted to beat the 15 competitors to the market. 16 Is that what you're saying? 17 MS. GERSTEL: Object to form. 18 A. I said what I said. 19 Q. Well, they wouldn't want the 20 competitors to get there first. 21 Right? 22 MS. GERSTEL: Object to form. 23 A. The competitors were there. 24 Q. Okay.</p> |
| <p style="text-align: right;">Page 139</p> <p>1 that name, no. 2 Q. How long did it take Ethicon to 3 get the TVT-O product to market? 4 A. I don't know. From first 5 thought to mind to market, I don't know 6 that answer. 7 Q. Is it ever a good idea to rush a 8 product to market? 9 MS. GERSTEL: Object to form. 10 A. The product's got to get to 11 market in a time frame that when it's felt 12 to be efficacious and safe. 13 Q. Have you ever reviewed any 14 Ethicon internal documents discussing how 15 quickly they got the TVT-O to market? 16 A. No. 17 Q. That's not something that was 18 ever provided to you? 19 A. Not that I recall. 20 Q. Of the opinions you -- 21 A. I'm going to correct that. 22 I seem to now have refreshed my 23 memory. I recall -- I can't recall 24 exactly. The theme of one company</p> | <p style="text-align: right;">Page 141</p> <p>1 The opinions you're giving in 2 this litigation with regard to the TVT-O, 3 TVT-A, TVT-Exact, have you ever published 4 those in any peer-reviewed journal? 5 A. No. 6 Q. Have you ever been involved in 7 any clinical trials comparing midurethral 8 slings to any other pelvic surgery? 9 MS. GERSTEL: Object to form. 10 A. Comparative trial, no. 11 Q. Have you ever been involved in a 12 randomized controlled trial involving 13 transvaginal mesh treatment of stress 14 urinary incontinence? 15 A. No. 16 Q. What antioxidants are added to 17 the TVT mesh slings? 18 A. I do not know. 19 Q. What is the pore size of the 20 Prolene mesh in the TVT products? 21 A. It's in the 1300 range. 22 Q. And it's the same for all of the 23 sling products we're talking about, right? 24 The TVT-O, the TVT-Abbrevio and the</p> |

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| <p style="text-align: right;">Page 142</p> <p>1 TVT-Exact?</p> <p>2 A. Yes.</p> <p>3 Q. Have you ever heard that pores</p> <p>4 in mesh collapse?</p> <p>5 A. I have not.</p> <p>6 Q. Do you agree that if mesh pores</p> <p>7 are not large enough, there can be an</p> <p>8 increased risk of infection?</p> <p>9 A. Yes.</p> <p>10 Q. Do you agree that if pores are</p> <p>11 not large enough, it increases the risk of</p> <p>12 erosion?</p> <p>13 A. Potentially, secondary to the</p> <p>14 first discussion we had about infection.</p> <p>15 Q. Do you agree that if pores are</p> <p>16 not large enough, there can be poor tissue</p> <p>17 integration that can cause mesh rejection?</p> <p>18 A. Yes.</p> <p>19 Q. Do you agree that you can get an</p> <p>20 infection with small pore mesh causing</p> <p>21 extrusion?</p> <p>22 A. Yes.</p> <p>23 Q. Do you agree that mesh with</p> <p>24 smaller pores tends to have a greater</p> | <p style="text-align: right;">Page 144</p> <p>1 say old construction mesh?</p> <p>2 MS. GERSTEL: Object to form.</p> <p>3 A. There are different ways the</p> <p>4 meshes were put together over time.</p> <p>5 They're woven differently. They have</p> <p>6 different fiber sizes, different pore</p> <p>7 sizes. So, you know, the Prolene mesh has</p> <p>8 a long history to it.</p> <p>9 So, the -- the way it was</p> <p>10 constructed was different in older, or</p> <p>11 let's say times past, was made differently</p> <p>12 than it is now.</p> <p>13 Q. Well, the mesh currently used in</p> <p>14 the TVT sling products was originally</p> <p>15 developed for hernia repair.</p> <p>16 True?</p> <p>17 A. Yes.</p> <p>18 Q. And it was developed for hernia</p> <p>19 repair in the gut.</p> <p>20 Fair?</p> <p>21 A. Yes.</p> <p>22 Q. It was not originally developed</p> <p>23 or designed to be implanted in the vagina.</p> <p>24 True?</p> |
| <p style="text-align: right;">Page 143</p> <p>1 inflammatory response than mesh with</p> <p>2 larger pores?</p> <p>3 MS. GERSTEL: Object to form.</p> <p>4 A. Yes.</p> <p>5 Q. What is the weight of the mesh</p> <p>6 in the TVT family of slings?</p> <p>7 A. I don't have that data.</p> <p>8 Q. Why does Ethicon call the</p> <p>9 Prolene mesh used in the TVT slings old</p> <p>10 construction mesh?</p> <p>11 MS. GERSTEL: Object to form;</p> <p>12 lack of foundation.</p> <p>13 A. I think terminology regarding</p> <p>14 the Ethicon family of meshes and names</p> <p>15 given to them have mistakes and confusion,</p> <p>16 and everything we're talking about in all</p> <p>17 four of these slings is type 1 wide pore</p> <p>18 mesh.</p> <p>19 MR. DeGREEFF: I'll move to</p> <p>20 strike as non-responsive. That wasn't</p> <p>21 the question that was asked.</p> <p>22 Q. My question was --</p> <p>23 MR. DeGREEFF: Strike that.</p> <p>24 Q. Do you know what I mean when I</p> | <p style="text-align: right;">Page 145</p> <p>1 A. Originally, yes.</p> <p>2 Q. And the mesh used in the TVT</p> <p>3 products was originally developed in 1974.</p> <p>4 Is that true?</p> <p>5 A. I don't have that knowledge of</p> <p>6 the date.</p> <p>7 Q. It was a long time ago, right,</p> <p>8 when it was developed?</p> <p>9 A. If that's the correct date, it's</p> <p>10 the number of years that it is. It's been</p> <p>11 working well for all these years.</p> <p>12 Q. It's almost a half century ago.</p> <p>13 Right?</p> <p>14 A. Yeah. It's been working well</p> <p>15 for 20 years.</p> <p>16 MS. GERSTEL: As someone who has</p> <p>17 gave birth close to that year, I take</p> <p>18 offense to that part.</p> <p>19 MR. DeGREEFF: Trust me, I'm</p> <p>20 real close to that too.</p> <p>21 Anybody need to take a break?</p> <p>22 MS. GERSTEL: Sure.</p> <p>23 (Recess taken.)</p> <p>24 (Lind Exhibit 7, Defense Expert</p> |

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| <p style="text-align: right;">Page 146</p> <p>1 General Report of Lawrence Lind, M.D. 2 re TVT, TVT-O, TVT-Exact and 3 TVT-Abbrevio, June 24, 2019, was marked 4 for identification, as of this date.) 5 (Lind Exhibit 8, Lawrence Lind 6 Supplemental General Materials List in 7 Addition to Materials Referenced in 8 Report, was marked for identification, 9 as of this date.) 10 BY MR. DeGREEFF: 11 Q. Sir, I'm handing you what has 12 been marked as Deposition Exhibit 7. 13 Can you tell us what that is? 14 A. It looks like my defense expert 15 general report for TVT, TVT-O, TVT-Exact 16 and TVT-Abbrevio. 17 Q. Sir, does this report contain 18 all of your opinions related to those 19 products? 20 MS. GERSTEL: Object to form. 21 A. No. 22 Q. What isn't in your report? 23 A. In preparing for the deposition, 24 I have continued to read, continued to</p> | <p style="text-align: right;">Page 148</p> <p>1 the materials you relied on in support of 2 your opinions. 3 Correct? 4 A. Correct. 5 Q. I'm talking about the opinions 6 you've given in your report, the general 7 opinions with regard to the TVT, TVT-O, 8 the TVT-Exact and TVT-Abbrevio. 9 Are all of those opinions that 10 you intend to give at trial contained in 11 this report? 12 A. Well, if the legal rules are 13 such that those are the limits, then those 14 will have to be the limits. 15 I have additional thoughts, and 16 you will guide me as to the legal process. 17 Q. Have you been asked by defense 18 counsel to provide any additional 19 opinions? 20 A. No. 21 Q. Is it your intention at trial to 22 provide any opinions that are not 23 contained in your report? 24 MS. GERSTEL: Object to form.</p> |
| <p style="text-align: right;">Page 147</p> <p>1 pull more articles, and continued to 2 educate myself. 3 Q. Sir, do you understand that in 4 this litigation, there's a deadline for 5 disclosing expert opinions? 6 A. Okay. 7 Q. Do you understand that deadline 8 has passed? 9 A. Okay. 10 Q. So, what opinions did you not 11 include in your report that you now intend 12 to offer? 13 A. I just have a little more detail 14 on some adverse events and some -- it's 15 really the studies are in there and it's 16 really just a little more in-depth 17 understanding of what the studies have 18 shown. 19 So, I'm not adding studies to 20 the report. I'm just a little more 21 familiar with the drill-down ordeal of 22 what's within the studies. 23 Q. I think we're talking about two 24 different things, and you're talking about</p> | <p style="text-align: right;">Page 149</p> <p>1 A. I will follow whatever the legal 2 guidelines are. And if I'm able to speak 3 opinions that are not specifically in 4 there, I will, and if I'm instructed that 5 I'm not allowed to do it, I'll follow the 6 instructions. 7 Q. Okay. Well, tell me what the 8 additional opinions are that you have as 9 you sit here that are not contained in 10 your report. 11 MS. GERSTEL: Object to form; 12 asked and answered. 13 A. There are details, there are 14 studies which I discuss in here and I give 15 opinions from those reports, and I have 16 more information from those same studies 17 which I feel is additive to my opinions. 18 Q. Do those studies, in any way, 19 alter your opinions? 20 A. They strengthen my opinions in 21 the same direction. 22 Q. So none of your opinions 23 contained in your report are going to 24 change?</p> |

| Page 150 | Page 152 |
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| <p>1 A. Correct.</p> <p>2 Q. So there is no new category of</p> <p>3 opinion that you plan to provide. What</p> <p>4 you're saying is you believe that you have</p> <p>5 a better understanding now of some of the</p> <p>6 materials you've -- or, I guess, materials</p> <p>7 you've already cited in your report.</p> <p>8 Fair?</p> <p>9 A. I think I have information that</p> <p>10 strengthens the opinions that I give.</p> <p>11 Q. Okay.</p> <p>12 But nothing will alter the</p> <p>13 opinions?</p> <p>14 A. Correct.</p> <p>15 Q. Have you prepared any kind of a</p> <p>16 supplemental report?</p> <p>17 A. No.</p> <p>18 Q. So, what is it that you want to</p> <p>19 add to the report that strengthens your</p> <p>20 analysis of these materials?</p> <p>21 MS. GERSTEL: Object to form.</p> <p>22 A. Well, for example, you know, a</p> <p>23 report quoted often is the Schimpf</p> <p>24 meta-analysis and a high rate of leg or</p> | <p>1 making that 16.7 percent, and the data</p> <p>2 from those trials clearly indicates that</p> <p>3 clearly the preponderance, or at least 90</p> <p>4 percent of the data shows that all of the</p> <p>5 pain goes away within a few weeks to a</p> <p>6 month. So, most of the data supporting</p> <p>7 that 16.7 is transient pain, which I think</p> <p>8 is very relevant as opposed to just the</p> <p>9 number of 16.7.</p> <p>10 In the Ford Cochrane analysis,</p> <p>11 which is also included several times in my</p> <p>12 report, supports that leg pain tends to be</p> <p>13 transient. So that's one example of an</p> <p>14 expansion or a deeper dive into a study to</p> <p>15 say what is the 16.7 percent in the</p> <p>16 Schimpf article mean, and doing some real</p> <p>17 research, we can say what's the body of</p> <p>18 literature that goes into the real number.</p> <p>19 Q. What other opinions do you want</p> <p>20 to add?</p> <p>21 A. I would say I've seen an article</p> <p>22 by Teo which is quoted and it certainly</p> <p>23 sparks a lot of attention because it's a</p> <p>24 trial where they decided to stop the</p> |
| Page 151 | Page 153 |
| <p>1 groin pain.</p> <p>2 Q. Okay.</p> <p>3 A. And that kind of jumped off the</p> <p>4 page at me as something that seemed out of</p> <p>5 line with a lot of the reading I have done</p> <p>6 and my personal experience. So I decided</p> <p>7 to explore that pain because I think we</p> <p>8 can all agree that if someone has an</p> <p>9 incision in the groin, it would make sense</p> <p>10 that they would have pain, some degree.</p> <p>11 Let's not say much degree. Anywhere you</p> <p>12 have an incision there's going to be pain</p> <p>13 immediately postoperatively.</p> <p>14 For the -- for the TVT, there's</p> <p>15 pain where the trocars come out of the</p> <p>16 suprapubic region. Right after and for</p> <p>17 the groin where it comes out. And what's</p> <p>18 of important interest is how severe is the</p> <p>19 pain and how long does it last. So that</p> <p>20 number that jumps off the page which a lot</p> <p>21 of people react to as a high leg pain</p> <p>22 rate, I wanted to explore that further.</p> <p>23 So I researched and found the seven</p> <p>24 randomized control trials that go into</p> | <p>1 trial, feeling it would be immoral to</p> <p>2 continue the trial because they had read</p> <p>3 other articles that showed a high</p> <p>4 incidence of groin pain and that it would</p> <p>5 be -- it would be immoral to continue the</p> <p>6 trial.</p> <p>7 I said well, let me look into</p> <p>8 it. It really seems, again, what was the</p> <p>9 data that was so alarming and what was</p> <p>10 going on in their study. And in their</p> <p>11 study, when they stopped the trial, almost</p> <p>12 all the patients who had groin pain had it</p> <p>13 resolved within a couple of weeks and</p> <p>14 there was only one patient who had chronic</p> <p>15 groin pain and it was a patient in the TVT</p> <p>16 group. So I thought it was very</p> <p>17 interesting that a study that is quoted</p> <p>18 often as how problematic that is a study</p> <p>19 had to be stopped because of the high</p> <p>20 level of groin pain reported elsewhere was</p> <p>21 in the middle of a study demonstrating</p> <p>22 extremely little groin pain and the only</p> <p>23 patient having prolonged problems was in</p> <p>24 the other group. So I think it's -- my</p> |

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| <p style="text-align: right;">Page 154</p> <p>1 main message is that if you dive into 2 deeper into the literature, the specifics 3 about the groin pain and how often it is 4 severe or prolonged very strongly is 5 compelling that the pain is transient. 6 Q. Okay. What else? What other 7 opinions do you want to add? 8 A. I would add an opinion on the 9 Okulu article. Okulu used Vypro and 10 absorbable mesh compared to two others for 11 a sling, and it's a very strongly 12 presented as evidence that there was a 13 better material, better alternative to the 14 TVT type mesh for slings. And I think 15 it's, number one, it's unreasonable to use 16 that as evidence that a TVT could be done 17 better with this material because the -- 18 in taking a deeper dive it became clear to 19 me that they don't do a procedure that 20 looks anything like a TVT. They make a 21 vaginal flap, a very large vaginal flap 22 and open a big incision, which TVT does 23 not. They cut out an island of vaginal 24 tissue and they sew a piece of this mesh</p> | <p style="text-align: right;">Page 156</p> <p>1 three articles, there are more articles in 2 the Vypro Pub Med search on using it for 3 mosquito netting than there are on using 4 it for slings. And the remainder of this 5 are related to non-incontinence 6 procedures. 7 So, I think it's -- my main 8 opinion that I'm adding is that the main 9 study used that's comparative is on a 10 procedure that doesn't resemble a TVT at 11 all. So I think it's unfair to say that 12 for a TVT this would be better. And that 13 the data that's available for Vypro in the 14 incontinence world is microscopically 15 small compared to unprecedented data in 16 favor of the TVT product which we're 17 discussing. So that's an additional 18 opinion I would give. 19 Q. How many of those articles 20 related to the TVT are long-term 21 randomized controlled trials with safety 22 as the primary endpoint? 23 MS. GERSTEL: Object to form. 24 A. About 85.</p> |
| <p style="text-align: right;">Page 155</p> <p>1 on top of the vaginal tissue and then they 2 use sutures it make a hammock out of it. 3 So, the procedure, while in that 4 study, I get that it showed that the 5 absorbable mesh had some favorable 6 characteristics compared to the 7 non-absorbable, it was describing a 8 procedure that someone invented that 9 doesn't exist anywhere else in the 10 literature. So I wanted to look a little 11 further into, you know, what is the 12 evidence for Vypro and the absorbable 13 meshes because the case that there's an 14 alternative that's more favorable is very 15 important, I think, to our discussion in 16 weighing the pluses and minuses here. 17 So I did a literature search on 18 Vypro mesh and there are 72 articles on a 19 Pub Med search. If you look for Vypro. 20 And while there are a -- if you research 21 midurethral sling, you'll get about 4,000 22 and when you research Vypro mesh, you'll 23 get 72. And there are precisely two 24 articles related to slings, and there are</p> | <p style="text-align: right;">Page 157</p> <p>1 Q. Which long-term randomized 2 control trials exist on the TVT? 3 MS. GERSTEL: Objection to form. 4 A. 417 had I believe 81 or 85 5 randomized controlled, I can't name them 6 all, and they had about 13,000 patients. 7 Q. Anything else you want to add? 8 I just want to know so I can 9 move to have them stricken. 10 MS. GERSTEL: I'm sorry? 11 MR. DeGREEFF: I just want to 12 know so I can move to have them 13 stricken. 14 BY MR. DeGREEFF: 15 Q. Doctor, were all these articles 16 that you're talking about now available to 17 you before you rendered your opinions in 18 this case? 19 A. The Okulu article was available 20 and is quoted in my paper, but in 21 reviewing my expert report and preparing 22 for this, I read through that article and 23 I -- when I noticed that it didn't look 24 anything like a sling and that it was new</p> |

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| <p style="text-align: right;">Page 158</p> <p>1 information for me, that it really was not 2 a minimally invasive TVT type procedure, I 3 said to myself gosh, if this is so 4 different, I'm curious how much we know 5 about this. So I looked further. 6 So, in reviewing my present 7 statements, new curiosities developed, so 8 I researched them. 9 Q. Yeah, that's information that 10 was available to you though prior to 11 issuing your opinions. 12 Right? 13 A. I guess the whole world of 14 articles was available to me. 15 Q. Nothing new came out between the 16 time you wrote your report and now. 17 Right? 18 A. Well, there have been articles 19 that have come out, but not -- I don't 20 think we're speaking about new articles 21 that came out that are relevant to your 22 discussion right now. 23 Q. None of the articles that you 24 have now reviewed and wish to add opinions</p> | <p style="text-align: right;">Page 160</p> <p>1 Those results are adverse to the 2 TVT products. 3 Right? 4 MS. GERSTEL: Object to form. 5 A. Well, I think they're -- I think 6 they're kind of good for my argument 7 because they -- Okulu really doesn't 8 describe a TVT procedure. So I would 9 consider it a strong defense that we're 10 trying to suggest something's an 11 alternative when it's really not doing the 12 procedure that we're interested in. 13 Q. No, I understand you think you 14 can attack those conclusions somehow. 15 But my question is the reason 16 you started looking into those articles is 17 because the results on their face are bad 18 for the TVT products. 19 True? 20 MS. GERSTEL: Object to form. 21 A. The studies didn't make sense to 22 me. The reason I looked at everything I 23 had in my report and if something came to 24 me that seemed curious or in question,</p> |
| <p style="text-align: right;">Page 159</p> <p>1 on were unavailable at the time you 2 originally authored your opinions. 3 True? 4 MS. GERSTEL: Object to form. 5 A. That's correct. 6 Q. This was something that you 7 decided to look into after having been 8 deposed previously on the TVT. 9 Is that fair? 10 A. Well, from a time sequence, it 11 would be after the TVT, but it wasn't from 12 the TVT that had me do it. I was reading 13 my report four days ago and these elements 14 just came to mind. So this was based on 15 things that came to mind in reading 16 through my report preparing this week. 17 Q. Because those articles that you 18 now seek to attack, those results are bad 19 for the TVT products. 20 Right? 21 MS. GERSTEL: Object to form. 22 A. Which articles are bad? 23 Q. The ones you're talking about 24 that you now wish to further clarify.</p> | <p style="text-align: right;">Page 161</p> <p>1 like the 16.7 percent erosion, it just 2 didn't seem right. So I'm a curious guy 3 and I look into things, and I looked into 4 it. I didn't go after it because it was 5 negative. I went after it 'cause it 6 didn't make sense to me. 7 Q. But it was negative. 8 Right? 9 A. I would say the Schimpf article 10 was misleading. 11 Q. Is 16.8 erosion rate, is that an 12 acceptable rate to you? 13 MS. GERSTEL: Object to form. 14 A. It's a rate that's misleading 15 because that's immediately postoperative, 16 and that's what's wrong with her data. 17 Q. I understand that you want to 18 attack an author who wrote something that 19 was actually published on the TVT 20 products. 21 My question is 16.8 percent 22 erosion, is that an acceptable erosion 23 rate to you? 24 MS. GERSTEL: Erosion?</p> |

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1 A. Are you speaking of erosion or
2 leg pain? Because the Schimpf --
3 Q. I'm sorry. Leg pain.
4 MR. DeGREEFF: Strike that.
5 Let's start over.
6 A. So, my answer to that would be
7 in the immediate postoperative period, I
8 think it's a very low rate of pain where
9 there's an incision and completely
10 acceptable.
11 If that is prolonged or severe
12 and prolonged, I would consider that
13 unacceptable.
14 Q. What is an acceptable rate of
15 chronic groin or leg pain?
16 A. Well, everyone would have a
17 different cutoff because you're balancing
18 the risks and benefits of each sling.
19 So, you know, I think that in
20 the 2 to 4 percent range is acceptable,
21 and we have to accept that in the
22 understanding that we are decreasing
23 bladder perforations, bowel perforations
24 with the TVTs. So it's not just does the

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1 patient have leg pain. It's what we're
2 trading.
3 MR. DeGREEFF: Move to strike
4 non-responsive.
5 Q. My question was just simply what
6 is an acceptable rate in your mind of
7 chronic groin and leg pain from a TVT
8 implant?
9 MS. GERSTEL: Object to the
10 form.
11 A. I would say in the 2 to 3
12 percent.
13 Q. So, your report, which is
14 Exhibit 7, is 57 pages long.
15 True?
16 A. Yes.
17 Q. I believe we discussed
18 earlier --
19 MR. DeGREEFF: Well, strike
20 that.
21 Q. Who wrote that report?
22 A. I did.
23 MS. GERSTEL: Objection.
24 Subject to privilege.

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1 BY MR. DeGREEFF:
2 Q. Did you write the whole thing?
3 MS. GERSTEL: Objection.
4 Subject to privilege under the Federal
5 Rules of Civil Procedure.
6 Don't answer.
7 MR. DeGREEFF: I can ask that.
8 I don't get to see drafts, but I can
9 ask who wrote it.
10 MS. GERSTEL: No, you can't ask
11 about the report writing process.
12 MR. DeGREEFF: I absolutely can,
13 but that's not where I'm going with
14 this anyway.
15 BY MR. DeGREEFF:
16 Q. Who wrote that report?
17 MS. GERSTEL: Objection.
18 Don't answer.
19 Subject to privilege.
20 BY MR. DeGREEFF:
21 Q. Are you going to choose to
22 accept your counsel's request that you not
23 answer my absolutely proper question?
24 A. Yes.

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1 MR. DeGREEFF: Moving forward,
2 you guys won't get anything from us.
3 BY MR. DeGREEFF:
4 Q. So, did you actually physically
5 write every word of it?
6 MS. GERSTEL: Objection. Same
7 basis.
8 Don't answer.
9 A. I'm declining to answer.
10 Q. Are there any parts of that
11 report that came from other people's
12 reports?
13 MS. GERSTEL: Same objection.
14 Don't answer.
15 MR. DeGREEFF: I absolutely can
16 ask that. That is 100 percent
17 correct. If he's pulled pieces of a
18 report from other individuals' expert
19 reports, I have every right to know
20 that.
21 MS. GERSTEL: It's all covered
22 by --
23 MR. DeGREEFF: No, it's not
24 covered by that.

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| <p style="text-align: right;">Page 166</p> <p>1 MS. GERSTEL: It is. 2 MR. DeGREEFF: No, it's really 3 not. 4 MS. GERSTEL: It is. I'm 5 directing him not to answer. 6 MR. DeGREEFF: Okay. 7 BY MR. DeGREEFF: 8 Q. Why do you think your counsel 9 doesn't want you to tell me who wrote your 10 report? 11 MS. GERSTEL: Objection. 12 A. I don't know whether there are 13 legal guidelines that she feels give that 14 that's the way it's supposed to go. 15 Q. Do you think if you wrote the 16 whole thing, she'd let you answer? 17 MS. GERSTEL: Objection. 18 Don't answer that. 19 A. I'm declining to answer. 20 Q. So, it took you 25 hours to 21 write a 57-page report. 22 Is that right? 23 A. Right. 24 Q. Your report also has a reliance</p> | <p style="text-align: right;">Page 168</p> <p>1 supplemented because you came up with 2 additional articles that you reviewed in 3 preparation for your deposition. 4 Is that true? 5 MS. GERSTEL: Object to the 6 form. 7 A. I think there's also one or two 8 that were in my report which we did not 9 have on there. So there were a couple of 10 articles that I added and a couple that 11 were erroneously that were not added that 12 were already on the report. 13 Q. Okay. 14 So, is everything -- 15 MR. DeGREEFF: Strike that. 16 Q. Does your supplemental reliance 17 list, together with your report, contain 18 everything that you reviewed in rendering 19 your general opinions? 20 A. As I stated previously, I have 21 read additional materials all week and 22 have some other things in my head, and I 23 do understand that you have legal reasons 24 for why I may or may not be able to use</p> |
| <p style="text-align: right;">Page 167</p> <p>1 list along with it. That's Exhibit 8. 2 Correct? 3 A. Right. 4 Q. Are you aware it was amended 5 five days ago? 6 A. I remember I had come up with 7 some articles that I had wanted to 8 include. 9 Q. What was added to it? 10 A. I don't recall specifically at 11 the moment. 12 Q. Who chose the materials that 13 were added to it? 14 A. I did. 15 Q. All of them? 16 A. All of them. 17 Q. Who drafted the additions to the 18 reliance list? 19 A. The reliance list, the typed 20 reliance list was done by counsel. 21 Q. Okay. 22 A. The input to the reliance list 23 this week was mine. 24 Q. So, this reliance list was</p> | <p style="text-align: right;">Page 169</p> <p>1 those, but -- so there would be some that 2 I reviewed that are not in there. 3 Q. Well, your reliance list was 4 just supplemented five days ago. 5 Have you reviewed additional 6 materials since then? 7 A. I have. 8 Q. The materials that you added to 9 your reliance list, were you directed by 10 counsel to look into certain issues? 11 MS. GERSTEL: Objection. 12 BY MR. DeGREEFF: 13 Q. Is that why you started to look 14 into them? 15 MS. GERSTEL: Objection. That's 16 will go under privilege. 17 Communications between experts and 18 counsel are privileged. 19 MR. DeGREEFF: That's a 20 privilege? 21 MS. GERSTEL: Yes, under the 22 rules. 23 We can look at it right now. 24 MR. DeGREEFF: Not if they rely</p> |

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1 on it.
 2 MS. GERSTEL: I'm sorry?
 3 MR. DeGREEFF: Not if they rely
 4 on it. If he takes actions what
 5 you're telling him to do.
 6 MS. GERSTEL: No, communications
 7 between expert and counsel are
 8 privileged.
 9 MR. DeGREEFF: If you provide
 10 information that's ultimately relied
 11 on, then I'm entitled to discovery.
 12 MS. GERSTEL: The communications
 13 are qualified under privilege except
 14 to the extent that they pertain to --
 15 MR. DeGREEFF: I'm not asking
 16 what was said. I'm asking if he was
 17 directed to do a search.
 18 MS. GERSTEL: That pertains to
 19 communication between me and him.
 20 MR. DeGREEFF: You and I are
 21 going to have to disagree on that.
 22 BY MR. DeGREEFF:
 23 Q. In rendering the general
 24 opinions that you've got in your report,

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1 is everything that you relied on in giving
 2 those opinions contained in your reliance
 3 list or the report itself?
 4 MS. GERSTEL: Object to the
 5 form.
 6 A. Say that again.
 7 Q. Is everything you relied on in
 8 rendering your opinions --
 9 MR. DeGREEFF: Strike that.
 10 Q. Are all the materials you relied
 11 on in rendering the opinions in your
 12 report contained in either your report or
 13 the supplemental reliance list?
 14 A. No, 'cause I also depend on
 15 knowledge learned from courses, books,
 16 reading, education, clinical experience,
 17 discussion with other experts, all the
 18 time I spent in R&D labs.
 19 So, my reliance is not just on
 20 articles. So I've had 25 years of
 21 learning that come from sources that are
 22 other than articles.
 23 Q. Let's try this again. I think
 24 if you listen to my question, it will be

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1 okay.
 2 Are all of the materials,
 3 materials, you're not a material, as far
 4 as I'm aware of, but are all of the
 5 materials you relied on in rendering the
 6 opinions in your report contained in
 7 either the supplemental reliance list or
 8 the report itself?
 9 A. When I go to courses, there are
 10 materials, entire binders that have
 11 information.
 12 Q. Are those on your reliance list?
 13 A. No. I've learned them over the
 14 years.
 15 Q. Why not?
 16 A. Because they're in my brain. I
 17 have them.
 18 Q. Do you understand that I have
 19 the right to understand and know about and
 20 see all of the materials you relied on in
 21 reaching your opinion?
 22 A. I think you're totally
 23 reasonable, and I am certainly not trying
 24 to be difficult. But when you say when I

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1 made opinions, what I have told you I also
 2 have from opinions which is the knowledge
 3 that's in my brain from the sum total of
 4 places I've gathered information, that's
 5 part of where my opinions came from.
 6 And if the word "materials" is
 7 something for us to focus on, in many of
 8 the places where I learned there were
 9 materials. I can't produce them. If that
 10 makes it illegal to be part of this, you
 11 know, you'll instruct me on that, and you
 12 and Diana will discuss that. But my
 13 opinions have a lot that comes from a lot
 14 of different sources of learning that
 15 don't have materials that can be put into
 16 the reliance list.
 17 Q. I want a copy of the materials
 18 you're talking about that I haven't seen.
 19 Do you have copies of them?
 20 A. I have some of them. Yeah.
 21 MR. DeGREEFF: I would like you
 22 to give your counsel all of them and
 23 then she can produce them to me.
 24 Is that okay with you?

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| <p style="text-align: right;">Page 174</p> <p>1 THE WITNESS: I'll give you what 2 I have, just clarifying that it won't 3 be the full complement of every 4 educational piece that I have. But I 5 do have quite a few. 6 MR. DeGREEFF: Whatever you 7 claim to be relying on, I want to see 8 a copy of it. So please give it to 9 your counsel. 10 MS. GERSTEL: Are you talking 11 about every textbook he read in 12 medical school? 13 MR. DeGREEFF: Right. Or at 14 least identify it. They haven't been 15 identified. 16 Well, I mean, if we're going to 17 play this game, we're going to play 18 this game. 19 MS. GERSTEL: I'm not trying to 20 play a game. 21 MR. DeGREEFF: If that's the way 22 we're going to play, if that is the 23 game you want to play, then that is 24 the game we're going to play.</p> | <p style="text-align: right;">Page 176</p> <p>1 I'm not going to show up with 2 binders and binders of things that you 3 haven't had a chance to look at in the 4 proper process. 5 MR. DeGREEFF: Well, if there 6 are materials that you are going to 7 rely on that are not on your reliance 8 list, identify them and give them to 9 your counsel, please. 10 BY MR. DeGREEFF: 11 Q. So, can you identify them right 12 now for me? 13 MS. GERSTEL: Objection. 14 A. There's binders and binders of 15 course materials I've taken every year I 16 take one or two courses. There's the -- 17 every year I update and I get the binder 18 for the female pelvic medicine fellowship 19 board certification course. It's, you 20 know, it's like three of these binders. 21 And, yeah, I mean, I'll get 22 you -- if you said you want everything 23 that I have, I'll get you everything I 24 have.</p> |
| <p style="text-align: right;">Page 175</p> <p>1 MS. GERSTEL: I'm not trying to 2 play a game. 3 I'm just saying that he's a 4 urogynecologist, and his opinions on 5 urogynecology are based in part on his 6 sum total of experience in practice 7 and in learning as a urogynecologist. 8 MR. DeGREEFF: That's not the 9 response to my question. My question 10 is very simple. 11 BY MR. DeGREEFF: 12 Q. What materials am I going to see 13 that you're going to talk about at trial 14 in support of your opinions that are not 15 included in either your reliance list, 16 your supplemental reliance list, or your 17 report? 18 A. Well, I would say if I rendered 19 the opinions from the items that I learned 20 outside of these materials that you have 21 in front of them, they're going to be 22 presented in the same way as part of my 23 experience and knowledge as a 24 urogynecologist.</p> | <p style="text-align: right;">Page 177</p> <p>1 BY MR. DeGREEFF: 2 Q. Are those things on your 3 reliance list? 4 A. Well, I would say that the 5 course, let's say the 2018 fellowship 6 review course binder instruction and 7 educational materials, that is not on my 8 reliance list. There are certainly 9 hundreds of articles from that course that 10 are on my reliance list because a number 11 of topics in that course are slings, 12 efficacy and safety of slings, and, you 13 know, all the sections that have to do 14 with mesh and slings are in that course. 15 I would ask if you like, if 16 we're going to do that, I would take out 17 the things that have to do with 18 constipation and, you know, things that 19 don't have to do with mesh or slings just 20 so that it's not like this (indicating). 21 But if you want it all, I'll follow 22 instructions. 23 Q. Right. So, this is not supposed 24 to be a difficult question. I mean, what</p> |

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| <p style="text-align: right;">Page 178</p> <p>1 I'm trying to figure out is what I'm going 2 to see at trial and what you're going to 3 discuss at trial.</p> <p>4 This is the supplemental 5 reliance list as I know it, and this is 6 what has been provided to us as the things 7 you relied on. And I am not including 8 your experience and learning and knowledge 9 and all those things because I understand 10 there's not a material for that.</p> <p>11 I'm trying to figure out what 12 materials that I'm going to look at at 13 trial or that you could potentially be 14 using at trial that are not included in 15 your supplemental reliance list or your 16 report.</p> <p>17 A. I think we can safely say what 18 you have in front of you are the 19 materials, or the scientific materials 20 that are going to come forward.</p> <p>21 I cannot separate the literature 22 from opinions I'm going to have based on 23 every other source and way that I learned, 24 that those are not going to be opinions.</p> | <p style="text-align: right;">Page 180</p> <p>1 for example the leg pain data, and it's 2 part of my knowledge that the articles 3 that comprise the 16.7 percent have 4 information X, Y and Z, I consider that 5 fair game.</p> <p>6 If it's not legally, you'll 7 inform me.</p> <p>8 Q. Okay.</p> <p>9 So, are you needing to update or 10 supplement your reliance list? Is that 11 what you're telling me?</p> <p>12 MS. GERSTEL: Objection.</p> <p>13 THE WITNESS: Am I supposed to 14 answer that?</p> <p>15 MS. GERSTEL: No, go ahead.</p> <p>16 A. If I had the opportunity, given 17 that your goal is to have everything that 18 would be presented, I would update it.</p> <p>19 Q. Can you update this and provide 20 me a final reliance list that will include 21 everything that you intend to rely on?</p> <p>22 A. I'd be happy to do that.</p> <p>23 And I promise that between now 24 and any subsequent time we meet there</p> |
| <p style="text-align: right;">Page 179</p> <p>1 But from the standpoint of materials, I 2 think you have what I'm going to present 3 to the court.</p> <p>4 The only clarification I would 5 give there is that these articles in and 6 of themselves have references. So those 7 references I would consider as part of 8 what I might reference. Meaning in the 9 bibliography of an article, it may 10 describe the articles that are supporting 11 itself, and I may speak to articles that 12 are in the bibliography that are not -- 13 that you don't have as a full.</p> <p>14 Q. So, it's your belief that by 15 disclosing an article as something you 16 relied on, that you're therefore 17 disclosing, for example if there's a 18 hundred citations for it, you're 19 disclosing all of those?</p> <p>20 A. Well, if I'm reading a Schimpf 21 article and we're discussing Schimpf and 22 we're discussing Schimpf which is an 23 article I've disclosed and it is relevant 24 to discussing the data that she discloses,</p> | <p style="text-align: right;">Page 181</p> <p>1 won't be ten more to add. So I would be 2 happy to, I think, come together on what 3 this discussion's been, and if was given 4 the opportunity to update it, I would add 5 about ten articles and we could call that 6 yes, you have in front of you the articles 7 I would rely on.</p> <p>8 Q. Okay.</p> <p>9 A. The materials.</p> <p>10 Q. Well, let's do that because I 11 want a final materials list. So, I mean, 12 that's the goal.</p> <p>13 A. Okay.</p> <p>14 MR. DeGREEFF: How soon can we 15 get that?</p> <p>16 THE WITNESS: In a few days.</p> <p>17 MS. GERSTEL: Yeah.</p> <p>18 MR. DeGREEFF: Okay. That's 19 fine.</p> <p>20 So, I'm going to mark a blank 21 document as Exhibit 9, and then we can 22 provide the supplemental materials 23 list to the --</p> <p>24 THE WITNESS: I'm making myself</p> |

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| <p>1 a homework note.</p> <p>2 MR. DeGREEFF: -- to the court</p> <p>3 reporter.</p> <p>4 Sir, for the record, can we</p> <p>5 agree that you are going to provide</p> <p>6 what is going to be a final reliance</p> <p>7 list to your counsel to be provided to</p> <p>8 me and the court reporter?</p> <p>9 THE WITNESS: Yes.</p> <p>10 MR. DeGREEFF: Thank you.</p> <p>11 And we will mark that as</p> <p>12 Deposition Exhibit Number 9.</p> <p>13 (Lind Exhibit 9, placeholder for</p> <p>14 production by the witness, was marked</p> <p>15 for identification, as of this date.)</p> <p>16 BY MR. DeGREEFF:</p> <p>17 Q. Looking at Exhibit 8, the</p> <p>18 current version of the supplemental</p> <p>19 reliance list, that reliance list is more</p> <p>20 than a hundred pages long.</p> <p>21 Right?</p> <p>22 A. I believe you.</p> <p>23 Q. Is it fair to say it includes</p> <p>24 thousands of documents and materials?</p> | <p>1 Q. Who chose the remaining 25</p> <p>2 percent?</p> <p>3 A. Counsel.</p> <p>4 Q. What was the methodology you</p> <p>5 applied for choosing the medical</p> <p>6 literature that was included in the</p> <p>7 reliance list?</p> <p>8 A. You know, I started -- I like to</p> <p>9 start on my own. I started on my own</p> <p>10 doing my Pub Med searches on the different</p> <p>11 products, then the different products plus</p> <p>12 complications, and from those choosing</p> <p>13 articles that I wanted. And when I got to</p> <p>14 areas where I felt that I was incomplete</p> <p>15 or didn't really have -- didn't seem to</p> <p>16 have authoritative understanding, I'd say</p> <p>17 do you have anything on this. Then they</p> <p>18 would provide materials.</p> <p>19 So, you know, it was kind of a</p> <p>20 back-and-forth. It was really -- I was</p> <p>21 trying to tell my story, and when my story</p> <p>22 had gaps, I said do we have more</p> <p>23 information that I'm not finding on this.</p> <p>24 It's hard when you try to do</p> |
| Page 183 | Page 185 |
| <p>1 A. Yes.</p> <p>2 Q. Who chose the documents on that</p> <p>3 reliance list?</p> <p>4 A. I chose the vast majority, and</p> <p>5 counsel suggested some additional.</p> <p>6 Q. You chose the vast majority of</p> <p>7 the internal Ethicon documents that are on</p> <p>8 that reliance list?</p> <p>9 A. No. Of the -- of the scientific</p> <p>10 literature.</p> <p>11 I didn't choose any of the</p> <p>12 Ethicon documents.</p> <p>13 Q. Okay.</p> <p>14 So, of the documents on your</p> <p>15 reliance list, is it fair to say that the</p> <p>16 portion you provided input on is the</p> <p>17 medical literature section?</p> <p>18 A. Yes.</p> <p>19 Q. And the remainder of it was</p> <p>20 chosen by defense counsel?</p> <p>21 A. The -- for the most part, yes.</p> <p>22 Q. What percentage of the medical</p> <p>23 literature would you say you chose?</p> <p>24 A. 75 percent.</p> | <p>1 a -- you know, the limitation where</p> <p>2 requests were made, it's really just a</p> <p>3 function of how large the literature is.</p> <p>4 When you put in midurethral slings, you</p> <p>5 get 4,000 on Pub Med. So, I was very,</p> <p>6 very diligent in preparing this report,</p> <p>7 but when going through 4,000 on a</p> <p>8 midurethral sling search and, you know,</p> <p>9 several hundred when you put in a TVT-O</p> <p>10 search, a TVT-O complication search, FDA,</p> <p>11 you know, notifications list, you know,</p> <p>12 it's just -- the reality is unless I had a</p> <p>13 full-time job, I could review 10,000</p> <p>14 documents and figure out which were</p> <p>15 relevant. So I pulled the ones which</p> <p>16 clearly looked right to me. I tried to</p> <p>17 point more towards the randomized</p> <p>18 controlled trials, that sort of thing.</p> <p>19 So, I created a story. And when</p> <p>20 the story had areas where I didn't feel I</p> <p>21 had good literature, I said do you have</p> <p>22 articles that I don't in this area, and</p> <p>23 they -- sometimes they said yes and</p> <p>24 sometimes they said no.</p> |

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1 Q. Did you ever inquire as to
 2 defense counsel's methodology for
 3 selecting the literature included in the
 4 reliance list?
 5 A. No.
 6 Q. I think you said you spent about
 7 40 hours reviewing the materials on the
 8 reliance list.
 9 Is that correct?
 10 A. Right.
 11 Q. Fair to say you did not review
 12 every document on that 102-page
 13 supplemental reliance list?
 14 A. I scanned the title of every
 15 article and decided which ones I wanted to
 16 look into further.
 17 Q. Okay. So, fair to say you did
 18 not review in detail every piece of
 19 medical literature included on that
 20 supplemental reliance list?
 21 A. That's fair to say.
 22 Q. Did you review all of the
 23 nonmedical literature documents?
 24 A. I'm not sure which ones you're

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1 referring to specifically.
 2 Q. Okay. Well, anything that's not
 3 designated as medical literature on your
 4 report, did you review all of those
 5 documents?
 6 MS. GERSTEL: Object to form.
 7 A. Well, I think I stated
 8 previously that I reviewed some Ethicon
 9 internal documents and did not review
 10 others.
 11 Q. So, it's reasonable to say that
 12 you didn't review everything on your
 13 reliance list.
 14 Right?
 15 MS. GERSTEL: Object to form.
 16 A. I read the titles of each and
 17 selected the ones I thought were most
 18 pertinent.
 19 Q. I'm not talking about just
 20 medical literature.
 21 I'm saying you didn't review all
 22 of the documents on this 102-page reliance
 23 list in 40 hours.
 24 Right?

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1 A. In detail, no.
 2 Q. That would have been essentially
 3 impossible?
 4 A. Thousands of hours.
 5 Q. Right.
 6 Would have taken thousands of
 7 hours to review all those, right?
 8 A. In detail to really read through
 9 an article in depth.
 10 Q. Because if you've got thousands
 11 of documents on your reliance list --
 12 A. It's ten minutes per, minimum.
 13 Q. Right.
 14 So you're looking at 10,000
 15 hours to review all those documents.
 16 Right?
 17 A. Correct.
 18 Q. And you essentially did what you
 19 could in 40 hours.
 20 Right?
 21 MS. GERSTEL: Object to form.
 22 A. I spent the time I felt
 23 necessary to do an excellent job on -- on
 24 the task, understanding that reading every

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1 item available on it provided in the world
 2 or on the reliance list was not possible.
 3 Q. What percentage of the medical
 4 literature on your supplemental reliance
 5 list did you actually review in detail?
 6 MS. GERSTEL: Object to form.
 7 A. In detail, I would say 30
 8 percent.
 9 Q. What percentage of the total
 10 documents on the reliance list, all of
 11 them including the internal documents and
 12 everything else that's on there, did you
 13 actually review in detail?
 14 MS. GERSTEL: Object to form.
 15 A. I can't give you a percentage on
 16 it.
 17 Q. How did you decide which
 18 articles to review in detail and which
 19 ones not to?
 20 A. The quality level of the study
 21 was the primary, meta-analysis, systematic
 22 reviews or randomized control trials, and
 23 then of course I was interested on the --
 24 I mean, I -- those are all the comparative

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| <p style="text-align: right;">Page 190</p> <p>1 trials. And then in those comparative 2 trials, I wasn't seeing a lot of themes 3 which I know are being proposed as 4 problems or negative aspects of some of 5 the products. So I looked for -- I did 6 a -- I did a search on complications. So 7 I went through complication articles on my 8 search and decided to pick out ones that I 9 should review that seemed to be at odds 10 with the randomized controlled trials. 11 Q. Did you review all of the 12 articles that were selected and provided 13 by defense counsel? 14 MS. GERSTEL: Object to form. 15 A. I would say I reviewed every 16 title and decided, based on the time frame 17 I had, which ones were relevant and 18 comprehensively reviewed a very good 19 fraction of them, but not all of them. 20 Q. You have on your reliance list 21 17 pages -- excuse me. On your 22 supplemental reliance list 17 pages of 23 what are referred to as production 24 materials. I think it's around page 75,</p> | <p style="text-align: right;">Page 192</p> <p>1 selection. 2 Q. Well, it's not a term I'm using. 3 It's a term that's on the reliance list. 4 A. Where is that term? 5 Q. At the top there (indicating). 6 A. It says "Production Materials." 7 So, let's see what we got here. 8 This would appear to be internal 9 documents describing various aspects of 10 bringing product to study, to develop, to 11 bring forward. 12 Q. Was today the first time you 13 knew there was a heading for production 14 materials on your supplemental reliance 15 list? 16 MS. GERSTEL: Object to form. 17 A. On the heading, I had not seen 18 the heading. 19 I've seen this list of 20 documents, and I've read a good fraction 21 of them. 22 Q. You didn't know there was a 23 heading because you didn't draft it. 24 Right?</p> |
| <p style="text-align: right;">Page 191</p> <p>1 if that helps. 2 A. In this document? 3 Q. Yes. In Exhibit 8. 4 A. Do you want to show me where 5 that is? 6 Q. I'll try. 7 (Pause.) 8 Q. I'll start over. 9 You have on Exhibit 8, which is 10 the supplemental reliance list that's 11 currently available, 17 pages of what are 12 referred to as production materials. 13 Do you see where I'm at? 14 A. Yep. 15 Q. And that's hundreds of documents 16 listed on there, right? 17 A. Yep. 18 Q. What qualifies as a production 19 material, for purposes of this reliance 20 list? 21 A. I don't know what definition 22 they give to qualify it as a production 23 document. It's a term you're using that 24 I'm not aware is how it's used for</p> | <p style="text-align: right;">Page 193</p> <p>1 MS. GERSTEL: Object to form. 2 A. I didn't know there was a 3 heading because when you turn it over, 4 it's so thick that it's covered by the 5 stapled area. 6 So, in looking over this to look 7 at each number, the heading on the page 8 was not particularly of importance to me 9 when I was reviewing it. 10 Q. I mean, you had seen the 11 supplemental reliance list before today. 12 Right? 13 A. Yes. 14 Q. Was there a staple on the page 15 then? 16 A. There was a clip or a staple or 17 something. 18 Q. Who selected the document -- 19 MR. DeGREEFF: Strike that. I 20 think we already talked about this. 21 Q. The documents included in this 22 production materials section were selected 23 by defense counsel. 24 Correct?</p> |

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| <p style="text-align: right;">Page 194</p> <p>1 A. The internal documents were all 2 selected by counsel. 3 Q. Did you review all of these -- 4 MR. DeGREEFF: Strike that. 5 Q. Did you review any of these 6 documents included in the production 7 materials section? 8 A. Yes. 9 Q. What percentage of them? 10 A. 20 percent. 11 Q. And how did you select which 12 documents you reviewed? 13 A. You know, based on what I was 14 reading. I asked for a number of topics. 15 I'd say, you know, tell me -- you know, I 16 was particularly interested in discussions 17 of laser-cut mesh. I said are there any 18 internal documents describing concerns 19 about the thigh and the obturator. 20 So, a good fraction of them were 21 things I came upon where I felt like I 22 wanted to know what was going on in the 23 decision-making, and then others were 24 offered by counsel.</p> | <p style="text-align: right;">Page 196</p> <p>1 an online database where all of the 2 documents were produced? Were you given 3 access to that online database so you 4 could do your own searches? 5 A. The online database, no. 6 Q. There's around 81 depositions on 7 your reliance list. It's towards the end. 8 It's after the production materials 9 section. 10 So, that is a section on your 11 reliance list that includes about 81 12 depositions. 13 Correct? 14 A. I'll trust your number. 15 Q. Does it look reasonable? 16 A. Yep. 17 Q. Fair to say you didn't read all 18 of those? 19 A. I did not read all of those. 20 Q. Who chose the depositions that 21 were included on this reliance list? 22 A. As stated previously, there are 23 certain topics I asked for, which would be 24 a smaller subset which -- which I asked</p> |
| <p style="text-align: right;">Page 195</p> <p>1 Q. Well, you didn't select any of 2 the internal documents. 3 Right? 4 MS. GERSTEL: Objection; asked 5 and answered. 6 A. I selected the topic. The 7 information and then the internal document 8 was provided on the several topics that I 9 asked about. 10 Q. Were you given any kind of 11 access to the document production database 12 so that you could do your own search for 13 documents? 14 A. I was given a binder of enormous 15 numbers of company documents, and I 16 discussed that I -- it would be impossible 17 for me to review all of them. So it would 18 have to be a combination of things I was 19 interested in and things that counsel 20 thought was most relevant for us to 21 discuss given reasonable but pretty 22 significant preparation. 23 Q. My question is, I apologize. 24 Were you given access to there's</p> | <p style="text-align: right;">Page 197</p> <p>1 for which generated some of these. 2 Now, they probably would have 3 been on the comprehensive list they were 4 planning to include, but I requested, 5 let's say, 10 or 20 documents, or 10 or 20 6 categories of documents and they were 7 provided, and the rest were electively 8 provided by counsel. 9 Q. For example, did you review Meng 10 Chen's depositions? 11 A. I don't recall. 12 Q. Who's Laura Angelini? 13 A. I don't recall. 14 Q. Did you read all of the Piet 15 Hinoul depositions? 16 A. I didn't read all of it. I read 17 some sections. 18 Q. How many of these depositions 19 did you actually read? 20 A. I would say I read parts of ten. 21 Q. Which ten? 22 A. Arnaud sounds familiar, Hinoul, 23 Charlotte Owens sounds familiar, David 24 Robinson.</p> |

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| <p style="text-align: right;">Page 198</p> <p>1 Q. Well, David Robinson sounds 2 familiar because I asked you about the 3 medical director Dr. Robinson earlier. 4 Correct? 5 MS. GERSTEL: Object to form. 6 A. No. I recall independently that 7 that was one of the ones that I had read. 8 Q. How did you select the 9 depositions that you read? 10 A. It would come up in a topic. It 11 would come up in a topic, you know, set up 12 as what was -- what was Ethicon concerned 13 about when they were making the obturator 14 sling, and then some deposition testimony 15 or internal documents were sent on that. 16 What other questions did I ask? 17 I was curious what the, you 18 know, lead directors of the 19 administration's opinions and thought 20 processes were on the topics that are 21 being raised in this litigation. So then 22 some of the directors' transcripts were 23 provided. 24 Q. So, did you review depositions</p> | <p style="text-align: right;">Page 200</p> <p>1 included in the reliance list? 2 A. I requested by topic 'cause I 3 didn't know the names of the players. 4 I mean, looking back, I remember 5 interacting with some of these people when 6 I was helping to teach some of their labs 7 and that sort of stuff, so I remember some 8 of the names, but I didn't have any reason 9 to select the names that I knew. There 10 were topics that I was interested in. 11 Q. Then there are six pages of, 12 quote, other materials, right after the 13 depositions. 14 A. Okay. 15 Q. What's included in the other 16 materials section? 17 MS. GERSTEL: Object to form. 18 A. This looks like authoritative 19 articles or materials from authoritative 20 entities, such as FDA, ACOG, AUA, the 21 other quality and research and scientific 22 administrative agencies and female pelvic 23 medicine. 24 There are some studies, a lot of</p> |
| <p style="text-align: right;">Page 199</p> <p>1 where Ethicon employees were expressing 2 concerns about making the TVT-O? 3 A. Yes. 4 Q. What was your understanding of 5 the concerns they were expressing? 6 A. They were concerned about groin 7 pain. 8 Q. Anything else they were 9 concerned about? 10 A. There were concerns whether the 11 laser-cut mesh was stiffer and if it was 12 stiffer, if it would change the behavior 13 and/or success or adverse reactions in the 14 procedure. 15 Q. And those were -- those concerns 16 were expressed in the -- by Ethicon 17 employees in the depositions you read? 18 A. I'm mixing together in my mind 19 the depositions versus e-mails. So this 20 is just -- to me it's just in my head as 21 internal documents. 22 Q. Okay. 23 Did you specifically request by 24 name any of the depositions that are</p> | <p style="text-align: right;">Page 201</p> <p>1 guidelines, position statements, bulletins 2 by the authoritative societies. 3 Q. Who chose those materials? 4 MS. GERSTEL: Objection. 5 A. Those are mostly by me. I had 6 put them in my report by my own 7 discretion. And I was being followed very 8 closely in our societies the growing, 9 growing support of the midurethral sling 10 based on its data, safety and efficacy 11 profiles. So the -- it was a very strong 12 part of my report was to -- it was a very 13 strong part of my report to -- so, these 14 are mostly requested by me because -- 15 either provided by me or requested by me 16 because they came across through my 17 societies with a very, very strong 18 repeated, repeated support for the case 19 for the midurethral sling being important 20 to preserve and important to clarify for 21 the educational world, the patient world. 22 Q. You asked for Dr. Elliott's 23 curriculum vitae? 24 A. No. Again, if we're going to go</p> |

| Page 202 | Page 204 |
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| <p>1 item by item, I can tell you whether I 2 requested it.</p> <p>3 I'm talking about the dominant 4 fraction of these are things that I 5 provided or requested. I did not request 6 all of them.</p> <p>7 Q. What percentage of them did you 8 request?</p> <p>9 A. The first page is about half. 10 The second page is a quarter. The third 11 page is a third. The page that's got 12 Daniel Elliott, I would say none.</p> <p>13 Q. Is it fair to say you requested 14 less than half of the materials included 15 in -- the documents included in the other 16 materials section of your reliance list?</p> <p>17 MS. GERSTEL: Objection to the 18 form.</p> <p>19 A. Somewhere between 30 and 50 20 percent.</p> <p>21 Q. And what percentage of these 22 materials did you actually review?</p> <p>23 A. The ones that I requested I 24 reviewed.</p> | <p>1 A. Got it.</p> <p>2 Q. Did you review all these expert 3 reports?</p> <p>4 A. I didn't review all of them, no.</p> <p>5 Q. Why was it important to you to 6 review expert reports?</p> <p>7 A. It would educate me on the 8 opinions of the plaintiff experts as to 9 what they felt was most relevant and what 10 the arguments were on the plaintiff's 11 side.</p> <p>12 Q. And which ones did you review?</p> <p>13 A. When I was doing my Prolift 14 general report, I read Garely and Elliott. 15 I remember those names. We had one 16 Rosenzweig report because it was 17 associated with one of the case-specific 18 reports. He was the case-specific expert, 19 so I read his report when I read that. So 20 I read three or four.</p> <p>21 Q. So you read three or four of the 22 maybe 30 or so that are on here?</p> <p>23 A. Right.</p> <p>24 Q. Did the plaintiff's expert</p> |
| Page 203 | Page 205 |
| <p>1 Q. And the rest of them were put on 2 the reliance list by defense counsel.</p> <p>3 Is that correct?</p> <p>4 A. Yes.</p> <p>5 Q. For example, there are some 6 things in the other materials that say, 7 for example, excerpts from Budke trial 8 transcript.</p> <p>9 Who would have done these 10 excerpts? Is that something you did?</p> <p>11 A. I don't know.</p> <p>12 Q. Who would have chosen the 13 excerpts that were used?</p> <p>14 A. I don't have the answer to that.</p> <p>15 Q. Do you remember reviewing any 16 excerpts from trial transcripts?</p> <p>17 A. There were one or two trial 18 transcripts which I did review. I can't 19 tell you which ones.</p> <p>20 Q. So, on the very last page of 21 Exhibit 8, your supplemental reliance 22 list, there's a number of expert reports 23 listed.</p> <p>24 Do you see that?</p> | <p>1 reports that you read reference documents 2 that were contrary to your opinions in 3 this case?</p> <p>4 A. Yes.</p> <p>5 Q. Are those documents, are they 6 referenced on your reliance list?</p> <p>7 A. I have a lot of -- I was pretty 8 good on my report about putting in, you 9 know, negative articles that are of 10 question.</p> <p>11 I would say that there are 12 negative articles in a more comprehensive 13 list on there. They're not all in my 14 report. But I did select articles which I 15 felt were either I found on my own or that 16 I was -- saw were focuses of plaintiff's 17 reports and chose to comment on them.</p> <p>18 Q. So the plaintiff's experts are 19 medical literature and documents in their 20 reports that were adverse or contrary to 21 your opinions that were not included on 22 your reliance list or in your report.</p> <p>23 True?</p> <p>24 MS. GERSTEL: Object to the</p> |

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| <p>1 form.</p> <p>2 A. Some are included and some are</p> <p>3 not included. Correct.</p> <p>4 Q. Did you review those documents</p> <p>5 or pieces of medical literature that were</p> <p>6 contrary to your opinions?</p> <p>7 A. I read through a good fraction</p> <p>8 of them on the reports that I read.</p> <p>9 Q. How did you get the internal</p> <p>10 documents that they referenced? Did you</p> <p>11 ask defense counsel for them?</p> <p>12 A. When I thought it was relevant.</p> <p>13 Q. Were those documents provided?</p> <p>14 A. When asked for, yes.</p> <p>15 Q. Did you pull each of the</p> <p>16 deposition citations in the plaintiffs'</p> <p>17 expert reports?</p> <p>18 MS. GERSTEL: Objection.</p> <p>19 A. I did not pull every one. I</p> <p>20 pulled a good fraction of them based on</p> <p>21 what the titles were and the time</p> <p>22 constraints.</p> <p>23 So the answer is I did not pull</p> <p>24 all of them. I pulled a very good</p> | <p>1 So, why are there so many</p> <p>2 documents on your reliance list if you're</p> <p>3 not relying on them?</p> <p>4 MS. GERSTEL: Objection to form.</p> <p>5 A. You know, in discussions, when</p> <p>6 we bring a topic and, you know, if I say</p> <p>7 that, you know, I've seen this internal</p> <p>8 document and I think it's relevant, I'd</p> <p>9 like to have access to the documents if I</p> <p>10 choose to review them. So then they are</p> <p>11 added.</p> <p>12 So, you know, there are times</p> <p>13 where I'm in the discovery process and</p> <p>14 putting together the report process and I</p> <p>15 say gosh, I see that there's this internal</p> <p>16 document that talks about X. I say well,</p> <p>17 I'd like to see internal documents that</p> <p>18 discuss, you know, A, B, C. So these are</p> <p>19 added. And then the ones that I see</p> <p>20 pertinent I review and the ones that just</p> <p>21 don't make the cut based on trying to do</p> <p>22 an excellent job, but having a body of</p> <p>23 literature and internal documents that's,</p> <p>24 you know, a four-year Ph.D. thesis worth</p> |
| Page 207 | Page 209 |
| <p>1 fraction of them.</p> <p>2 Q. Of the deposition excerpts?</p> <p>3 A. The depositions, I'm sorry.</p> <p>4 The expert reports was a good</p> <p>5 fraction. The deposition excerpts, if</p> <p>6 there was a reference to an internal -- a</p> <p>7 few. A few. I can't say that was</p> <p>8 comprehensive. And the deposition reports</p> <p>9 at times were so extensive, you know, it</p> <p>10 could be a week-long deposition that</p> <p>11 sometimes the purpose of that review was</p> <p>12 not to comprehensively understand all the</p> <p>13 depositions that went on. It was to get a</p> <p>14 flavor for what kind of discussions, you</p> <p>15 know, the employees, the administrators</p> <p>16 were having related to the topic, just to</p> <p>17 get a flavor for what was going on</p> <p>18 internally there. They're extremely long</p> <p>19 and not possible to drill down on and</p> <p>20 examine comprehensively.</p> <p>21 So I would say on the expert</p> <p>22 reports, I pulled a good fraction. On the</p> <p>23 deposition reports, a very small number.</p> <p>24 Q. Okay.</p> | <p>1 of true deep dive, you have to make your</p> <p>2 choices.</p> <p>3 Q. I mean, fair to say you're</p> <p>4 obviously not relying on them if you</p> <p>5 haven't reviewed them.</p> <p>6 Right?</p> <p>7 MS. GERSTEL: Object to form.</p> <p>8 A. I am not relying on articles</p> <p>9 that I haven't reviewed.</p> <p>10 Of course I would ask the</p> <p>11 question am I permitted to review those</p> <p>12 and use them moving forward, but I guess</p> <p>13 this is really not the place for that</p> <p>14 question. I'll take that up with counsel.</p> <p>15 Q. Yeah. I'll let you take that up</p> <p>16 with her.</p> <p>17 I want to look at Exhibit 7,</p> <p>18 which is your report, if you don't mind.</p> <p>19 A. Sure.</p> <p>20 Q. On page 15 under</p> <p>21 "Complications."</p> <p>22 Are you following me?</p> <p>23 A. Mm-hm.</p> <p>24 Q. There's a section where you say:</p> |

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| <p style="text-align: right;">Page 210</p> <p>1 Surgeons should also advise their patients 2 of their own success and complication 3 rates as well as rates that are published 4 in the peer-reviewed literature. In our 5 practice, the complication rates with TVT, 6 TVT-O, TVT-Exact, and TVT-Abbrevio are 7 infrequent, and almost without exception 8 complications can be resolved with the 9 patient remaining content and pain free. 10 Did I read that correctly? 11 A. Yes. 12 MS. GERSTEL: I'll just state it 13 was continent, not content. 14 MR. DeGREEFF: Continent. 15 That's a great point. Content is 16 different. 17 BY MR. DeGREEFF: 18 Q. So, is it your intention to give 19 opinions on complication rates with the 20 TVT products in your practice? 21 A. The main thrust of giving 22 opinions on complication rates comes from 23 the enormous data. 24 In my practice, I have not</p> | <p style="text-align: right;">Page 212</p> <p>1 I will state from my practice of 2 seeing them regularly and insuring that 3 they come back at those intervals, that I 4 feel very confident that my efficacy and 5 safety reflects that of the literature. 6 Q. Okay. So, I think that was a 7 long way of saying, and maybe I'm wrong, 8 but I think it was a long way of saying 9 that you are not going to give opinions 10 regarding your personal complication rates 11 in your practice. 12 A. I don't think that's what I said 13 at all. 14 MS. GERSTEL: Objection. 15 BY MR. DeGREEFF: 16 Q. Okay. Well, how do you track 17 the success and complication rates in your 18 patients? What's your systematic method? 19 MS. GERSTEL: Object to form. 20 A. The patients are not recorded in 21 a long-term spreadsheet with data. 22 My way of tracking complications 23 is making sure they come back. And 24 there's a reminder on the electronic</p> |
| <p style="text-align: right;">Page 211</p> <p>1 collected the patients and organized them 2 in a systematic trial where I've 3 quantified, reviewed and seen how many 4 come back and systematically recorded 5 their efficacy and safety. 6 It is our routine practice to 7 have them come back at three months, six 8 months, one year and two years, and the 9 patients come back in high frequency. Do 10 I know it's 99 percent? Do I know it's 90 11 percent? I don't. I know it's a high 12 fraction. I know that the patients are -- 13 I know that the complication rates are 14 low. 15 We have a quarterly Pelvic 16 Surgeon Society meeting in Manhattan, and 17 we have an agreement with all the local 18 experts where, maintaining patients' 19 confidentiality, we will let each other 20 know if problems and complications have 21 come in that we're not aware about. 22 So, I don't have an organized 23 statistical study to tell you on my 24 patients.</p> | <p style="text-align: right;">Page 213</p> <p>1 medical record, if they don't make the 2 appointment, we call them to come back, 3 and we get back well over 90 percent of 4 our surgical patients at a year or two 5 years. 6 So, I know and I see them at one 7 year and two years and I know if they're 8 having problems. So, if I have a -- my 9 own patients and I have 90 to 95 percent 10 of them back and I have to do one mesh 11 exposure, I feel pretty confident that my 12 mesh exposure rate is doing well. It is 13 not statistically quantified, but it is, 14 by virtue of the surveillance in our 15 office, pretty tightly assured that I'm 16 seeing over 90 percent of my patients 17 back. 18 Q. So, this is essentially 19 anecdotal. You don't have any spreadsheet 20 or statistical analysis or tracking system 21 with regard to complications with mesh 22 patients that you can point me to or show 23 me? 24 MS. GERSTEL: Object to form.</p> |

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| <p style="text-align: right;">Page 214</p> <p>1 A. I can point you to the number of 2 cases I've done and the number of mesh 3 erosions that have been revised. I can 4 statistically quantify. 5 I can quantify, I can search for 6 bladder injury and I can quantify that and 7 give it to you over an N, which would be 8 the total number. I can quantify 9 prolonged catheterization due to voiding 10 dysfunction. 11 So, these are all -- 12 Q. Well, you need a numerator and a 13 denominator, right? 14 A. Mm-hm. 15 Q. How do you track your patients 16 that are lost to follow-up? 17 A. I would have to see if they -- 18 on the EMR if they showed up. 19 Q. So, all of this you're talking 20 about is not an analysis that you've done 21 currently. 22 True? 23 A. Correct. 24 Q. You don't have any kind of</p> | <p style="text-align: right;">Page 216</p> <p>1 that are lost to follow-up, true? We 2 don't know what their ultimate results 3 were? 4 A. We call all of them back, and we 5 get almost all of them back. We get over 6 90 percent of them back. That I know. 7 And most studies of two years don't do 8 better than 90 percent. 9 Q. What I'm hearing you say, and I 10 think what we agree on, is that you have 11 not done any kind of formal analysis and 12 you have no tracking system in place with 13 regard to the complications for your 14 patients related to the TVT products. 15 True? 16 MS. GERSTEL: Object to form. 17 A. I would say I haven't done a 18 formal analysis. I would say I have a 19 tracking system to insure that I'm 20 capturing my patients. 21 Q. And that tracking system is just 22 you know how many of your patients have 23 come back? 24 MS. GERSTEL: Object to form.</p> |
| <p style="text-align: right;">Page 215</p> <p>1 internal registry tracking your patients 2 to see what complications they've had 3 over, say, a five-year period? 4 A. That is correct. 5 The preponderance of my opinion 6 is based on the 4,000 articles on 7 midurethral slings that are published. 8 Q. That's different. 9 You being able to opine about 10 literature is different. I'm asking about 11 your personal complication rates. 12 You have no systematic method in 13 place at your facility for tracking 14 complication rates and those that are lost 15 to follow-up. 16 True? 17 MS. GERSTEL: Object to form. 18 A. I have a systematic method of 19 following up to make sure that over 90 20 percent of my patients return and I know 21 how they're doing. It is not recorded, 22 collected, and it has not been made into a 23 study with a numerator and a denominator. 24 Q. And you haven't tracked patients</p> | <p style="text-align: right;">Page 217</p> <p>1 A. Right. And then I know -- and I 2 know on those patients if they have 3 problems. 4 Q. What does the literature say 5 about the average rate of patients that 6 are lost to follow-up? 7 A. It's quite variable. 8 Q. How do you track the 9 complication rates in your patients with 10 regard to specific mesh products? 11 A. Well, I use the same mesh 12 products most commonly. 13 Q. For example, what's your 14 tracking system on the number of TVT-Os 15 that have been implanted and whether they 16 have had complications or not? 17 A. The system would be the same as 18 I recorded -- as I responded before, is I 19 would have the patients back and see how 20 they're doing. 21 Q. Okay. 22 A. It's not systematic, but it's 23 systematic that they come back. 24 Q. How do you track whether the</p> |

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1 mesh implanted in your patients is
 2 mechanical or laser cut?
 3 MS. GERSTEL: Object to form.
 4 A. I know the products I'm using.
 5 Q. For example, if you use TVT-O,
 6 how do you know whether you've used a
 7 mechanical-cut or laser-cut TVT-O? How do
 8 you track that?
 9 A. It's marked on the box.
 10 Q. Yeah. But what's your tracking
 11 system?
 12 A. I don't care which one it is.
 13 Q. So there isn't one, right?
 14 A. It's not a clinically relevant
 15 distinction for me.
 16 Q. My question was a little
 17 different than that.
 18 My question is there is no
 19 tracking system in place for your patients
 20 with regard to whether there's been
 21 mechanical or laser-cut mesh used.
 22 True?
 23 A. True.
 24 Q. You implant Ethicon slings as

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1 part of your practice.
 2 Right?
 3 A. Yes.
 4 Q. How many, let's start with just
 5 slings first, how many slings would you
 6 say you've implanted since you started
 7 using them?
 8 MS. GERSTEL: Object to form.
 9 A. It's in the 2800 to 3500 range.
 10 Q. And we're talking about mesh
 11 slings, right?
 12 A. Yes.
 13 Q. When did you first begin
 14 implanting mesh slings in women?
 15 A. Well, the TVT we first started
 16 implanting in 2000, but we had been doing
 17 some patch cut slings with suture before.
 18 So there was some modifications. But in
 19 terms of the TVT slings and the slings --
 20 the midurethral slings that were created
 21 to be individual units and made for that
 22 purpose, around that time.
 23 Q. That was in? I didn't catch the
 24 time. Late '90s or 2000?

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1 A. 2000.
 2 Q. Which of the TVT line of slings
 3 have you implanted?
 4 A. I have implanted all of them.
 5 Q. So you've implanted the TVT?
 6 A. Mm-hm.
 7 Q. The TVT-O?
 8 A. Mm-hm.
 9 Q. The TVT-Abbrevio?
 10 A. Yes.
 11 Q. And the TVT-Exact?
 12 A. Yes.
 13 Q. Which of those do you currently
 14 use?
 15 A. I use the TVT-Exact.
 16 Q. When did you stop using the TVT?
 17 A. I was an avid TVT user, and then
 18 I liked the idea of a smaller needle. I
 19 thought the procedure could be done with a
 20 smaller needle. So I proposed that to
 21 Ethicon. They declined that idea. So I
 22 proposed it to Boston Scientific, and they
 23 made the Advantage Fit. So when the
 24 Advantage Fit came out and was a very -- I

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1 thought very similar in every way with a
 2 number of very nice changes that I liked,
 3 I switched to the, staying retropubic, I
 4 switched to the Advantage Fit.
 5 Q. Okay.
 6 And that is a Boston Scientific
 7 product?
 8 A. Correct. And then --
 9 Q. And when did you switch to that
 10 from the TVT?
 11 A. I don't know exact time. Four
 12 years later, five years later.
 13 Q. So in 2004, 2005?
 14 A. 2005, 2006 range.
 15 Q. So you have not used the TVT
 16 since 2006?
 17 A. I still use the TVT-Exact.
 18 Q. Right.
 19 But you haven't used the TVT,
 20 was my question?
 21 A. Correct.
 22 Q. And what were the advantages of
 23 the -- I guess what was better about the
 24 Advantage Fit Boston Scientific sling

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| <p style="text-align: right;">Page 222</p> <p>1 versus the Ethicon TVT?</p> <p>2 MS. GERSTEL: Object to form.</p> <p>3 A. I liked that it had blue sleeves</p> <p>4 over the introducer, which were easier to</p> <p>5 see in the bladder if you had a bladder</p> <p>6 perforation. The other color could get</p> <p>7 lost in the background of the bladder and</p> <p>8 be missed.</p> <p>9 I liked that the blue tubes</p> <p>10 allowed you to twist and untwist the sling</p> <p>11 so when that it's wrapped around the</p> <p>12 urethra and there are little tiny twists</p> <p>13 to it, you could align it more perfectly.</p> <p>14 And I liked that it was 2.3</p> <p>15 millimeters instead of 5. That was a</p> <p>16 significantly, significantly different</p> <p>17 smaller needle.</p> <p>18 Q. So, the smaller needle was --</p> <p>19 what's the advantage of the smaller</p> <p>20 needle?</p> <p>21 A. It's, you know, it passes</p> <p>22 through the tissues easier. It makes a</p> <p>23 smaller puncture in the skin. You need a</p> <p>24 smaller exit. And it lets you -- again,</p> | <p style="text-align: right;">Page 224</p> <p>1 There are times when you're</p> <p>2 getting to your final moment when you're</p> <p>3 going to decide is the sling exactly where</p> <p>4 I like it fit, how loose is it, how tight</p> <p>5 is it, how is it lying flat. And there</p> <p>6 are times where one arm doesn't seem to be</p> <p>7 perfectly parallel with the other arm.</p> <p>8 And once you've gone through with the</p> <p>9 product, if it just has a sheathe on it,</p> <p>10 you can't rotate it. You can't straighten</p> <p>11 those out.</p> <p>12 So this is just a visual, a</p> <p>13 visual thing that aesthetically looks like</p> <p>14 if you want a sling to lay around, you'd</p> <p>15 like it to look like that rather than</p> <p>16 slightly turned. So those tubes, because</p> <p>17 they had some memory to them, allowed you</p> <p>18 to make those turns and adjustment and</p> <p>19 have the mesh visually appear to be</p> <p>20 flatter. When you pulled it through the</p> <p>21 canals they seemed a little bit askew.</p> <p>22 Q. These are the tubes on the</p> <p>23 Advantage Fit?</p> <p>24 A. Yes.</p> |
| <p style="text-align: right;">Page 223</p> <p>1 the subtleties of the case require you to</p> <p>2 move this needle, thread it between the</p> <p>3 bladder and the pubic bone, and when you</p> <p>4 fail, you get a bladder perforation. So</p> <p>5 with the smaller needle, I felt, based on</p> <p>6 the cadaver labs, that you could thread</p> <p>7 that space a little more easily and then</p> <p>8 if you do get a puncture in the bladder,</p> <p>9 you get a 2.3 millimeter puncture instead</p> <p>10 of a 5. So when you take it out, the</p> <p>11 bladder constricts at that point. And I</p> <p>12 felt that I did like that -- you know,</p> <p>13 when you did have a bladder perforation</p> <p>14 inadvertently, I liked that I went through</p> <p>15 with a needle that was half the size.</p> <p>16 Q. And then what is the -- you said</p> <p>17 that the Advantage Fit, the Boston</p> <p>18 Scientific product, allowed for better</p> <p>19 alignment of the sling versus the TVT?</p> <p>20 A. Well, the data and the results I</p> <p>21 was having on the TVT and the data I was</p> <p>22 aware of spoke to the fact that however</p> <p>23 that kit is made to work, it's working</p> <p>24 extremely well.</p> | <p style="text-align: right;">Page 225</p> <p>1 Q. Why is it important for the</p> <p>2 tensioning to be correct on the sling?</p> <p>3 A. Well, because every sling --</p> <p>4 every single sling ends up too loose, just</p> <p>5 right, or too tight. So you got to use</p> <p>6 the teaching on how to do the procedure</p> <p>7 and to leave it truly tension free to try</p> <p>8 to get the results that the original</p> <p>9 procedure was producing.</p> <p>10 Q. What happens if there's too much</p> <p>11 tension on a sling?</p> <p>12 A. In the mild case, the patient</p> <p>13 would have a little difficulty voiding,</p> <p>14 need a catheter for a couple of days. In</p> <p>15 a moderate case, she'll need it for a</p> <p>16 week. And in a more significant case,</p> <p>17 she's not able to regain normal voiding</p> <p>18 function and you have to release the</p> <p>19 sling.</p> <p>20 Q. And by release it, you mean</p> <p>21 removal or revision surgery?</p> <p>22 A. Yes. There are some people who</p> <p>23 describe in the short-term as putting a</p> <p>24 obturator in the urethra and pulling</p> |

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| <p style="text-align: right;">Page 226</p> <p>1 downward to loosen it. And there's little 2 data on that and I don't favor that. But 3 yes, I would generally be talking about 4 revision surgery if they had retention. 5 Q. And these things you liked about 6 the Advantage Fit by Boston Scientific 7 were things that you had brought to 8 Ethicon and they declined to do? 9 A. Only the narrow needle was my 10 idea. The things having to do with the 11 tube were theirs. 12 Q. And the needle was important for 13 reducing the extent of surgical 14 complications. 15 Is that kind of the deal? 16 A. Yeah. 17 Q. Which is a patient safety issue? 18 A. Yes. 19 Q. So, when did you start 20 implanting the TVT-O? 21 A. I started implanting about a 22 year after it was released. 2005, 2006. 23 Q. Did you implant -- I mean, how 24 many TVT-Os would you say you've</p> | <p style="text-align: right;">Page 228</p> <p>1 the case you could switch. So it was very 2 flexible in terms of what you could use it 3 for. It was quite a bit of a cost and it 4 met many doctors' needs all at once. So 5 we trimmed down our product line and gave 6 up the TVT-O. 7 Q. And when was that? 8 A. I can't tell you exactly. It 9 was -- I don't know exactly. 10 Q. Last five years? Last ten 11 years? 12 A. I would say five years ago to 13 six years ago. 14 Q. Did you compare the Caldera to 15 the -- the Caldera is a sling. 16 Correct? 17 A. Yes. 18 Q. And was it the Desara that you 19 chose? 20 A. Yes. 21 Q. And is it -- did you, before 22 choosing it and eliminating the TVT-O at 23 your hospital, did you look into the 24 safety and efficacy comparison at all?</p> |
| <p style="text-align: right;">Page 227</p> <p>1 implanted? 2 A. About 150 to 200. 3 Q. At some point, did you stop 4 using the TVT-O? 5 A. I did. 6 Q. When was that? 7 A. We -- we were approached with a 8 problem with cost issues where we had 9 seven or eight doctors and each one 10 wanting three different slings. So the 11 hospital had an inventory which they felt 12 was impossible, and they said we need you 13 to get together with your data, individual 14 preferences and options for slings and 15 come up with what you want. 16 And the Caldera, I had seen the 17 Caldera product line and it was very, very 18 favorable in our review. It was favorable 19 because of cost. It was favorable because 20 it comes with one piece of mesh that can 21 affix to reusable instruments that let you 22 do every sling, inside-out sling, 23 outside-in sling, top-down retropubic, 24 bottom-up retropubic, all. At any time in</p> | <p style="text-align: right;">Page 229</p> <p>1 A. We used it in a lab about 20 2 times and looked at it in the hand and 3 looked at biochemical properties and 4 determined it was not the same, but very 5 similar. 6 At that point when Caldera had 7 come out, we really had data from most of 8 the sling products that they were 9 relatively equivalent in efficacy and 10 safety. 11 In answer to your question, they 12 did not have significant data on it, no. 13 Q. When did you start using the 14 TVT-Abbrevo? 15 A. You know, when it came out, the 16 concept was appealing and I would 17 alternate between my slings, giving it a 18 try. I used it probably 30 or 40 times. 19 I thought it was a very nice sling. I 20 thought I was -- with my other obturator 21 slings, I wasn't having groin pain. 22 So, I kind of thought to myself 23 we have some data on Abbrevo. It's 24 clearly not going through all the same</p> |

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| <p>1 tissues. So we have the potential 2 advantage that it's not going all the way 3 through the muscles, so maybe there will 4 be less leg groin pain, but how well is it 5 anchored.</p> <p>6 We did have some studies to show 7 relevant equivalency to full-length 8 obturator slings, but I felt that from 9 doing obturator slings and not having 10 groin pain other than from the first week 11 or two, I felt more secure having a 12 full-length sling. So I just decided 13 mostly to stay with that.</p> <p>14 I do occasionally order it just 15 for the sake of fellow teaching to show 16 the variety of the sling.</p> <p>17 Q. The TVT-Abbrevio is not a 18 full-length sling.</p> <p>19 Correct?</p> <p>20 MS. GERSTEL: Object to the 21 form.</p> <p>22 A. Correct.</p> <p>23 Q. How long is the TVT-Abbrevio?</p> <p>24 A. I don't know the exact length.</p> | <p>1 Q. Yeah, that wasn't my question.</p> <p>2 My question is is it fair to say 3 that the TVT-Abbrevio is closer in length 4 to the TVT-S mini sling than it is to the 5 TVT full-length slings?</p> <p>6 MS. GERSTEL: Objection.</p> <p>7 A. I would actually say no, I 8 disagree with that because let me -- I 9 will say out of the box the answer is yes, 10 but when you talk about the full-length 11 TVT is meant to be very, very long so that 12 if you have an obese patient, the mesh can 13 emerge from the abdominal wall which has 14 very variable size. So when you talk 15 about how much is cut off and how much is 16 left in the body, I would suggest that the 17 length of the mini TVT or the TVT Secure, 18 which is going to the undersurface of the 19 pubic bone where it's at a junction with 20 the obturator muscle, and the TVT-Abbrevio 21 is going to perforate the muscle, those 22 are, you know, a centimeter apart.</p> <p>23 In terms of the part that's left 24 in the patient, I think they're probably</p> |
| Page 231 | Page 233 |
| <p>1 I'd guess at 12 or 15, but I don't know 2 the exact length.</p> <p>3 Q. I think your report does. I 4 think it's 12 centimeters, according to 5 your report.</p> <p>6 A. Yeah, that's what I recall.</p> <p>7 Q. Does that sound accurate?</p> <p>8 A. Sounds about right.</p> <p>9 Q. What is the length of a 10 full-length TVT sling?</p> <p>11 A. I think it's in the 23 to 25. 12 Somewhere in that range.</p> <p>13 Q. And what was the length of the 14 TVT-S, the mini sling?</p> <p>15 MS. GERSTEL: Objection.</p> <p>16 A. That, I don't know. That was 17 shorter. I didn't use many of those.</p> <p>18 Q. Fair to say that the TVT-Abbrevio 19 is closer in length to the TVT-S mini 20 sling than it is to the full-length TVTs?</p> <p>21 MS. GERSTEL: Objection.</p> <p>22 A. I'd have to put the numbers on 23 paper, but I don't think the size 24 comparison is the relevant issue.</p> | <p>1 pretty similar.</p> <p>2 Q. When did you start using the 3 Abbrevio?</p> <p>4 A. 2006.</p> <p>5 Q. When did you stop?</p> <p>6 A. 2010.</p> <p>7 These are approximates.</p> <p>8 Q. Yeah, sure.</p> <p>9 You said you were more 10 comfortable using a full-length sling. 11 Why is that?</p> <p>12 A. To be clear, my vast 13 preponderance of slings are retropubic, 14 and the reason for that is I started using 15 it in 2000. I had 600, 800 cases done 16 before any obturator sling came out. I 17 was thrilled with my results. I went from 18 doing a Burch with a full incision with an 19 open laparotomy to the TVT sling, which 20 was 15 minutes. I was not hitting the 21 bladder 'cause my skills are good. I was 22 getting extremely low complication rates. 23 So I had something that the patients 24 were -- had very fast recovery. Took me</p> |

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| <p style="text-align: right;">Page 234</p> <p>1 15 minutes to do. And when the obturator 2 came out, I said to myself that's pretty 3 cool. That's very interesting. I'm going 4 to select my patients to do that when I 5 have anatomy that gives me a reason not to 6 do the one I like because the one I like 7 it would be hard for me in my personal 8 experience to improve upon it because 15 9 minutes, loving my results and almost 10 complication free, no reason to change. 11 So, I used my -- mostly did my 12 obturator slings when someone had a 13 hernia, had a previous hernia repair, they 14 had a previous retropubic surgery like a 15 Burch or a Marshall-Marchetti, abdominal 16 wall surgery with mesh, reasons to stay 17 away from the target zone for the 18 retropubic regular TVT. 19 Q. Again, I appreciate that. My 20 question was different though. 21 My question was your testimony 22 earlier was that you felt more comfortable 23 with a full-length sling. 24 Why would you prefer a</p> | <p style="text-align: right;">Page 236</p> <p>1 the Abbrevio. Does it hold as well. So I 2 said the Abbrevio is not going through all 3 the anchoring tissues. So, since I'm not 4 having groin problems, I'll stay with the 5 full-length sling because I don't feel I 6 need to move away from a groin pain 7 problem because I wasn't having it. 8 Q. Okay. 9 Yet the TVT-Abbrevio was brought 10 up by Ethicon in response -- it was 11 supposed to reduce the groin pain 12 associated with the TVT-O and other 13 obturator devices. 14 True? 15 A. Yes. 16 THE WITNESS: I'm going to take 17 a break just for the bathroom, if I 18 may. 19 (Recess taken.) 20 BY MR. DeGREEFF: 21 Q. When did you begin using the 22 TVT-Exact? 23 A. When it came out, I was using 24 Caldera and I was using the Advantage Fit.</p> |
| <p style="text-align: right;">Page 235</p> <p>1 full-length sling over a shorter sling? 2 MS. GERSTEL: Object to form. 3 A. Well, in the case of the 4 retropubic -- are we talking obturator or 5 retropubic or just across the board? 6 Do you want to break it down? 7 Q. I'm talking about the 8 TVT-Abbrevio. 9 A. The Abbrevio. 10 So, I wasn't having any 11 significant groin pain past the immediate 12 perioperative period with the full-length 13 sling. So, since I wasn't having problems 14 with the potential problem with the 15 full-length sling, the only reason to go 16 to Abbrevio is that you're concerned with 17 groin pain or you're having groin pain and 18 you want to see if you can reduce that by 19 having a thread going through instead of a 20 piece of mesh. 21 So, since I wasn't having the 22 pain that would lead you to Abbrevio, I 23 said to myself I have some studies, but 24 they're very early studies and few about</p> | <p style="text-align: right;">Page 237</p> <p>1 So I mixed it in for teaching purposes. I 2 liked the idea that I was getting the 3 Ethicon product back because, you know, it 4 owned the data. So now we kind of took 5 the things that Advantage Fit had kind of 6 changed that I liked. I really liked the 7 slimmer needle for my, again, teaching 8 situation, residents and fellows. So now 9 I had the original with a slimmer needle 10 and with tubes. So that we kind of 11 brought back the two things. So I started 12 using that a bit more frequently. 13 Q. And you started that when? 14 A. Pretty soon after it came out. 15 I usually -- most things I'm the kind of 16 person that says let my other expert 17 buddies get 50, 70 cases done and make 18 sure everybody's having a nice time with 19 it and then I join in. 20 Q. And how many have you put in at 21 this point, do you think? 22 A. Three hundred. 23 Q. And how many, I never asked you, 24 how many of the original TVT did you put</p> |

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| <p style="text-align: right;">Page 238</p> <p>1 in?</p> <p>2 A. That was before there was a</p> <p>3 competitor. So like ten to -- like 500 to</p> <p>4 600.</p> <p>5 Q. The TVT and the TVT-Exact are</p> <p>6 placed by retropubic approach.</p> <p>7 Correct?</p> <p>8 A. Yes.</p> <p>9 Q. And the TVT-O and the TVT-A were</p> <p>10 transobturator approach?</p> <p>11 A. Yes.</p> <p>12 Q. I think we may have talked about</p> <p>13 this already, but it's all a blur because</p> <p>14 it's been four hours.</p> <p>15 The transobturator approach has</p> <p>16 a higher re-operation rate.</p> <p>17 Correct?</p> <p>18 A. Yes.</p> <p>19 Q. It's understood typically that</p> <p>20 the slings placed using the transobturator</p> <p>21 approach are less durable than those using</p> <p>22 the retropubic.</p> <p>23 True?</p> <p>24 MS. GERSTEL: Object to the</p> | <p style="text-align: right;">Page 240</p> <p>1 and answered.</p> <p>2 A. I am aware that there are</p> <p>3 studies showing that. I don't believe</p> <p>4 that that is the collective data of all</p> <p>5 the meta-analysis, but there are studies</p> <p>6 that do show that.</p> <p>7 Q. Okay.</p> <p>8 When you were implanting the</p> <p>9 TVT-O and the TVT-Abbrevio, did you advise</p> <p>10 your patients that there was a potential</p> <p>11 increased risk with the obturator</p> <p>12 approach?</p> <p>13 MS. GERSTEL: Object to form.</p> <p>14 A. I advised them of both</p> <p>15 techniques, and I advised them of</p> <p>16 advantages and disadvantages of both. So</p> <p>17 I did include the proposed advantages of</p> <p>18 the TVT-O, and I did tell them the</p> <p>19 proposed adverse reactions associated with</p> <p>20 each, because they have a little different</p> <p>21 profile, each of the slings.</p> <p>22 Q. What were the differences in</p> <p>23 potential adverse events between the TVT</p> <p>24 and the TVT-O?</p> |
| <p style="text-align: right;">Page 239</p> <p>1 form.</p> <p>2 A. The data's mixed on that. There</p> <p>3 are RCTUs that show them to have equal</p> <p>4 efficacy at two and five years, and there</p> <p>5 are RCTs that show some better durability</p> <p>6 of the TVT-O over time. That's as I</p> <p>7 recall the literature.</p> <p>8 Q. Of the greater durability of the</p> <p>9 retropubic over time?</p> <p>10 A. Right. But that's not the</p> <p>11 dominance of the data. The preponderance</p> <p>12 of the data shows relatively equivalent</p> <p>13 rates, and Ford and Cochrane's analysis</p> <p>14 shows that.</p> <p>15 Q. So the data shows that the</p> <p>16 devices placed via the retropubic approach</p> <p>17 are equally or more durable than those</p> <p>18 placed via the transobturator.</p> <p>19 Correct?</p> <p>20 A. Yes.</p> <p>21 Q. Are you aware of studies finding</p> <p>22 the rate of re-operation twice as high</p> <p>23 with the transobturator approach?</p> <p>24 MS. GERSTEL: Objection; asked</p> | <p style="text-align: right;">Page 241</p> <p>1 A. So, the TVT has a higher</p> <p>2 incidence of organ injury, bladder injury</p> <p>3 and voiding dysfunction.</p> <p>4 The TVT-O has a higher incidence</p> <p>5 of vaginal sulcus perforation, sometimes</p> <p>6 called an angle needle introduction, groin</p> <p>7 pain, I would usually describe to them as</p> <p>8 typically transient and in rare cases</p> <p>9 prolonged, and with those being the major</p> <p>10 differences.</p> <p>11 Q. Was the major reason for those</p> <p>12 differences the retropubic versus the</p> <p>13 transobturator approach for placement?</p> <p>14 A. It was the anatomic pathway?</p> <p>15 Q. Would the problems associated --</p> <p>16 that you would have told your --</p> <p>17 MR. DeGREEFF: Strike that.</p> <p>18 Q. Would the differences from an</p> <p>19 adverse event standpoint between the TVT</p> <p>20 and the TVT-Abbrevio have been similar to</p> <p>21 the ones we just discussed?</p> <p>22 A. I think they would be similar,</p> <p>23 but I think the data bears out, and it</p> <p>24 makes sense, that you would have a</p> |

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| <p style="text-align: right;">Page 242</p> <p>1 somewhat lesser chance of having groin 2 pain. 3 Q. Do you consent the patients to 4 the implant procedure prior to implanting 5 mesh slings? 6 MS. GERSTEL: Object to form. 7 A. Hundred percent. 8 MR. DeGREEFF: What's the 9 objection? 10 MS. GERSTEL: I'm sorry? 11 MR. DeGREEFF: What's the 12 objection? 13 MS. GERSTEL: You said do you 14 consent patient to the implant 15 procedure. I'm a little confused by 16 exactly what you mean by that. 17 But my objection's on the 18 record. 19 BY MR. DeGREEFF: 20 Q. As part of your consent process, 21 you explain to them the risks and 22 complications that Ethicon mesh slings can 23 cause? 24 A. Yes.</p> | <p style="text-align: right;">Page 244</p> <p>1 but it's rare. 2 Q. And what about dyspareunia, do 3 you advise them of the potential for 4 chronic and ongoing dyspareunia? 5 A. I do. 6 Q. Exposure and erosion, what is 7 exposure and erosion? 8 A. Well, you could probably ask ten 9 experts and get ten different answers, but 10 I would put it this way. 11 Exposure, literally the 12 definition of the word means you can see 13 the mesh. So, let's say the wound is open 14 somewhere. How it got opened we're not 15 talking about, but you can see the mesh. 16 In erosion you're also seeing 17 mesh. And I would say the distinction I 18 make when you try to think of 19 pathophysiology is that when you do a 20 vaginal procedure, you make a single 21 incision through a very thin tissue. As 22 opposed to the belly where you go through 23 three or four layers. So it is a 24 dependent position, and you cannot put a</p> |
| <p style="text-align: right;">Page 243</p> <p>1 Q. What risks and complications do 2 you tell them are associated with the 3 TVT-O? 4 A. The TVT-O, I tell them you can 5 have bleeding. You can have pain. You 6 can have dyspareunia. You can have groin 7 pain that is usually transient, but can, 8 in some cases, be longer standing and 9 require revision. You could require 10 revision for a failure of the procedure, 11 for the procedure being too tight. I 12 inform them of the chance of 13 exposure-slash-erosion. I tell them 14 there's a chance of voiding dysfunction. 15 There's a chance of puncture of the 16 urethra or the bladder. 17 Q. Those are all complications that 18 could be caused by the TVT-O mesh sling. 19 True? 20 A. Yes. 21 Q. When you advise them about pain, 22 do you advise them about the potential for 23 chronic pain? 24 A. I tell them there's a potential,</p> | <p style="text-align: right;">Page 245</p> <p>1 wound dressing on it to support it like 2 you do elsewhere. So it is vulnerable to 3 fluid collecting. 4 I'll try to speed this up. 5 A wound can open and if a wound 6 opens and you have a wound failure because 7 your enclosure wasn't good or you had some 8 fluid collection, the wound opens. Then 9 you'll have an exposure. To me that 10 usually looks like the -- the wound looks 11 innocent. It doesn't show signs of 12 inflammation, of an active process. It 13 just looks like a wound that's separated. 14 When I think of erosion, I think 15 of a more active process. The body didn't 16 like the material that was in there or it 17 got infected. There's a reaction going on 18 and the tissue looks much different. It 19 looks inflamed. It looks like it's 20 pushing it out as opposed to the walls of 21 the wounds that opened and the exposure 22 that's just kind of dangling there free. 23 And in an erosion everything there seems 24 to be more of an active process.</p> |

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| <p style="text-align: right;">Page 246</p> <p>1 So, I don't think there's a</p> <p>2 strict scientific or medical definition of</p> <p>3 it. I try to look at it this way, and</p> <p>4 that's from the vaginal exposure.</p> <p>5 In terms of an erosion into the</p> <p>6 urethra or into the bladder, you know,</p> <p>7 those are even tougher because, you know,</p> <p>8 in the case I described to you, you can</p> <p>9 just have a wound that opens. So</p> <p>10 hypothetically, on an erosion to an</p> <p>11 internal organ, the mesh is moving from</p> <p>12 one place to another. It was my strong</p> <p>13 belief that most erosions to internal</p> <p>14 organs were there when the patient left</p> <p>15 the operating room.</p> <p>16 Q. Mesh can lead to mesh erosion.</p> <p>17 True?</p> <p>18 MS. GERSTEL: Object to form.</p> <p>19 A. I would say that I've never seen</p> <p>20 a mesh placed in the right place lead to</p> <p>21 erosion if erosion is an active process.</p> <p>22 Q. You can't have mesh erosion or</p> <p>23 mesh exposure without mesh.</p> <p>24 Fair?</p> | <p style="text-align: right;">Page 248</p> <p>1 you don't have to go through them all</p> <p>2 again.</p> <p>3 With regard to the TVT-Exact,</p> <p>4 how would the -- when you -- the</p> <p>5 complications that you tell your patients</p> <p>6 are caused by the TVT-Exact, how would</p> <p>7 that be different than the TVT-O?</p> <p>8 A. I tell them they're very</p> <p>9 similar. I say this is an evolution of a</p> <p>10 device and this one is a little bit</p> <p>11 slimmer. Other than it being slimmer,</p> <p>12 it's the exact same procedure. I feel in</p> <p>13 my hands that it lets me go through the</p> <p>14 spaces a little more easier, and if there</p> <p>15 is an inadvertent puncture of the bladder,</p> <p>16 which does happen in a few percentage</p> <p>17 cases, I like the fact that the hole is</p> <p>18 smaller and it heals spontaneously.</p> <p>19 Q. Other than those differences,</p> <p>20 would the complications caused by the</p> <p>21 TVT-Exact that you consent your patients</p> <p>22 to be the same as what we discussed with</p> <p>23 the TVT-O?</p> <p>24 A. Yes.</p> |
| <p style="text-align: right;">Page 247</p> <p>1 A. Right. Correct.</p> <p>2 Q. And transvaginal mesh can cause</p> <p>3 foreign body reaction, right? Like we</p> <p>4 talked about earlier.</p> <p>5 A. Yes.</p> <p>6 Q. And that can cause inflammation?</p> <p>7 A. Yes, it can.</p> <p>8 Q. And that can cause chronic pain?</p> <p>9 A. It can.</p> <p>10 Q. Are the complications that you</p> <p>11 tell your patients are associated or</p> <p>12 caused by the TVT-Abbrevio similar to what</p> <p>13 you advise them on the TVT-O?</p> <p>14 A. I explain to them the</p> <p>15 difference. I explain that they have a</p> <p>16 light -- a likelihood, but not -- of less</p> <p>17 chance of having groin pain, but not no</p> <p>18 chance.</p> <p>19 Q. But other than groin pain, would</p> <p>20 the other complications that we talked</p> <p>21 about being caused by the TVT-O remain the</p> <p>22 same for the TVT-Abbrevio?</p> <p>23 A. Yes.</p> <p>24 Q. I'm just trying to make it so</p> | <p style="text-align: right;">Page 249</p> <p>1 Q. And the things we've discussed,</p> <p>2 these complications we've discussed with</p> <p>3 regard to that you consent your patients</p> <p>4 on for the TVT products, those are things</p> <p>5 that are not good for the patients.</p> <p>6 Right?</p> <p>7 MS. GERSTEL: Object to form.</p> <p>8 A. Well, when I'm consenting them</p> <p>9 and telling them a list of adverse</p> <p>10 reactions, by definition adverse reactions</p> <p>11 are not good for the patients, but they're</p> <p>12 a known risk and they're part of</p> <p>13 risk-benefits of trying to get the benefit</p> <p>14 of being dry.</p> <p>15 Q. As part of your practice, you</p> <p>16 treat women suffering from complications</p> <p>17 caused by mesh slings.</p> <p>18 Right?</p> <p>19 A. I do.</p> <p>20 Q. In fact, you're at a tertiary</p> <p>21 care hospital.</p> <p>22 Right?</p> <p>23 A. Yes.</p> <p>24 Q. And you're actually referred</p> |

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| <p style="text-align: right;">Page 250</p> <p>1 mesh complications from other places in 2 the State of New York. 3 Right? 4 A. I am. 5 Q. Are there any other states other 6 than New York that you receive referrals 7 of women suffering from mesh complications 8 from? 9 A. 1996 I -- well, before the 10 mesh -- you still had other meshes then, 11 but, you know, '96 to 2005 I was one of, 12 like, five people in the area. So I had 13 people from multiple, multiple states. So 14 now we've got good trained people in a lot 15 of places, so they come from far less 16 often, but I still will get people from 17 New Jersey, Pennsylvania, Upstate New 18 York. 19 Q. Okay. 20 There are doctors in referral 21 centers like yours for women suffering 22 from mesh complications in states all over 23 the United States. 24 Correct?</p> | <p style="text-align: right;">Page 252</p> <p>1 decrease you're referring to slings or 2 vaginal mesh or both? 3 Q. I'm referring, in that question, 4 I was referring to transvaginal mesh, 5 period. 6 A. So, then no. I would correct my 7 answer. I'm sorry. 8 Yes, I think with the removal 9 and direction not to use those products 10 and taken off, it's decreased the access. 11 And I certainly wish they'd do 12 that to the machine guns that have been 13 going off in the last couple of weeks. 14 Q. What complications caused by 15 mesh slings do you treat in your practice? 16 A. Retention, obstruction, 17 exposure-slash-erosion, dyspareunia. I'm 18 not seeing a lot of groin pain. 19 Occasionally urethral erosion. 20 Q. How about chronic UTI? 21 A. The chronic UTI is a tough one 22 when you have to try to attribute it to 23 mesh when you see patients that have 24 slings in place that have chronic UTI.</p> |
| <p style="text-align: right;">Page 251</p> <p>1 A. There are many now, yes. 2 Q. And how many referrals a year do 3 you receive from women suffering from mesh 4 complications? 5 A. It's decreased quite a bit over 6 the last five years. I think over the 7 last five years the people knowing how to 8 do them right are doing them more often 9 and people whose techniques perhaps 10 weren't as good are doing them less often. 11 So I would say right now I get 12 between five and ten a year. 13 Q. Do you know what mesh products 14 have been pulled off the market in the 15 last five years? 16 MS. GERSTEL: Object to form. 17 A. I might not be able to name them 18 all, but I know a lot of them. 19 Q. Do you think that has anything 20 to do with the decrease in the number of 21 women you're seeing with mesh 22 complications? 23 A. No. 24 Pardon me. Referring to</p> | <p style="text-align: right;">Page 253</p> <p>1 So, if you have something 2 related to the mesh that explains it, so 3 they're retaining urine and they're not 4 emptying and the natural flow process and 5 cleansing process isn't working, you know, 6 you say releasing this would probably 7 help. 8 It's sometimes hard when you get 9 a patient who has chronic UTIs and there's 10 no obstruction. They empty well. The 11 cystoscopy's clear. There's no exposure. 12 They're not behaving inflamed or infected. 13 So it's hard. Sometimes we have to make 14 decisions that we don't see something that 15 would make sense that it would be from the 16 sling and you have to judge that. 17 So when there's an obstruction 18 and retention, makes sense. Obviously 19 when there's a piece of mesh in the 20 bladder, makes sense. 21 We do have situations where 22 patient comes in and says I have 23 infections, is this from my mesh. And we 24 do our assessment and I don't find</p> |

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| <p style="text-align: right;">Page 254</p> <p>1 something that logically attributes to it, 2 and you have to decide what to do with it. 3 Q. Have you seen pieces of mesh in 4 the bladder? 5 A. Yes. 6 Q. How about inflammation, you 7 treat women suffering from inflammation 8 from mesh? 9 A. Whether the patients come with, 10 like I said, exposure, erosion, most of 11 them are quiet exposure. They notice it 12 because either they felt it when they were 13 touching themselves or the partner felt 14 it. Most of the time mesh exposure is 15 found innocently. They didn't know it was 16 there. 17 When you talk about 18 inflammation, I would say in a small 19 fraction of the exposure-slash-erosions 20 they come in and it seems hotter. That's 21 the one I would say where I was speaking 22 before I'd say this seems to be more of a 23 this one's being extruded because it seems 24 like an active process and they're</p> | <p style="text-align: right;">Page 256</p> <p>1 So not a true exposure, but as 2 uncomfortable. So sometimes we have to 3 release the side band. I've had to do one 4 groin exploration. 5 Q. What do you mean by "groin 6 exploration"? 7 A. An obturator sling who had 8 discomfort by the groin that it was 9 persistent. 10 Q. Have you done removals or 11 revisions related to the TVT mesh 12 products? 13 A. The retropubic? 14 Q. Any of the products in the line. 15 A. Yes. 16 Q. How many? 17 A. 20 to 30. 18 Q. Mesh slings, generally speaking, 19 how many removal or revision surgeries do 20 you think you've done? 21 A. In total? 22 Q. Yes. 23 A. I haven't quantified it. It's 24 five to ten a year now. It was ten a year</p> |
| <p style="text-align: right;">Page 255</p> <p>1 sensitive and inflamed. But that's a 2 minority. 3 Q. But I think the answer is yes, 4 you do treat women that have inflammation 5 caused by mesh? 6 A. Yes. 7 Q. Do you perform surgery to treat 8 transvaginal mesh complications? 9 A. Yes. 10 Q. How about treatment of 11 transvaginal mesh complications caused by 12 mesh slings? 13 MS. GERSTEL: Object to form. 14 A. Yes. 15 Q. What kind of surgeries do you 16 perform? 17 A. If they're too tight, I loosen 18 them. If they're in the bladder, we take 19 it out of the bladder and repair the 20 bladder. If it's in the sulcus and it's 21 uncomfortable with vaginal pain, we have 22 to refresh the sulcus and sometimes the -- 23 you might be through into the vagina and 24 sometimes it might be behind the vagina.</p> | <p style="text-align: right;">Page 257</p> <p>1 earlier. 2 I would say hundred to 150. 3 Q. So, you currently do five to ten 4 mesh sling removals per year? 5 A. Some kind of revision. 6 Q. What are typically the 7 indications for revision of the TVT mesh 8 sling products? 9 A. The number one indication truly 10 is that their doctor saw it and told them 11 that your mesh is exposed, you should have 12 it taken out. So they come asymptomatic 13 and worried about their mesh. So we have 14 a chat about if you're okay and you're 15 fine and you're not having any symptoms, 16 you don't have to do anything about it. 17 Half of those patients will say let's get 18 it out, I don't want it there. And half 19 will say hey, if I'm feeling great, let's 20 leave it. 21 So, the most common indication 22 is referred from a physician for something 23 they didn't know about 'cause they -- the 24 physician -- their primary care OB-GYN saw</p> |

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| <p style="text-align: right;">Page 258</p> <p>1 an exposure.</p> <p>2 Q. So the most common is they're</p> <p>3 referred for mesh exposure?</p> <p>4 A. Yeah.</p> <p>5 Q. And what other indications lead</p> <p>6 to removal of the TVT mesh slings?</p> <p>7 A. They have pain or dyspareunia or</p> <p>8 the partner felt something.</p> <p>9 Q. And you've revised TVT mesh</p> <p>10 slings based on all of those indications.</p> <p>11 True?</p> <p>12 A. I wouldn't be able to say for</p> <p>13 every single one of those indications</p> <p>14 there was a TVT product. That's -- that's</p> <p>15 too exact to say that for every one of</p> <p>16 those it was a TVT.</p> <p>17 You know, they come and</p> <p>18 sometimes we could have the op report;</p> <p>19 sometimes we don't. Sometimes we know</p> <p>20 exactly which sling it was; sometimes we</p> <p>21 don't. We do our best to get operative</p> <p>22 reports. Sometimes we get them; sometimes</p> <p>23 we can't. Sometimes they've had stuff</p> <p>24 done in another country.</p> | <p style="text-align: right;">Page 260</p> <p>1 Have you ever seen a patient</p> <p>2 with mesh that is roped, curled, frayed,</p> <p>3 deformed, folded or wrinkled?</p> <p>4 A. I've never witnessed those</p> <p>5 things.</p> <p>6 Q. Do you agree that those things</p> <p>7 increase the risk of pain for a woman?</p> <p>8 A. I don't know that those have</p> <p>9 been assessed in the patient in a study.</p> <p>10 These all seem to be things of excised</p> <p>11 mesh and I think the mesh sits differently</p> <p>12 in the body when it's excised. So I don't</p> <p>13 see it roped and curled and all of that.</p> <p>14 It takes the shape of the tissue it's in.</p> <p>15 Q. So you've never seen or never</p> <p>16 treated a patient that had mesh that was</p> <p>17 deformed?</p> <p>18 A. How do you define "deformed"?</p> <p>19 Q. How do you define "deformed"?</p> <p>20 You're the doctor.</p> <p>21 A. I will say on some prolapse</p> <p>22 cases, if you have a piece of mesh that's</p> <p>23 attached and the attachment released, so</p> <p>24 if the procedure fails, then the -- then</p> |
| <p style="text-align: right;">Page 259</p> <p>1 Q. These would all be examples of</p> <p>2 reasons you've revised mesh slings.</p> <p>3 True?</p> <p>4 A. Yes.</p> <p>5 Q. What percentage of your practice</p> <p>6 is related to treating transvaginal mesh</p> <p>7 complications?</p> <p>8 MS. GERSTEL: Object to the</p> <p>9 form.</p> <p>10 Is that all transvaginal mesh?</p> <p>11 MR. DeGREEFF: Right.</p> <p>12 MS. GERSTEL: I'll just object</p> <p>13 to the extent it's outside the scope</p> <p>14 of this deposition.</p> <p>15 A. I'd see about 200 a month. I'll</p> <p>16 see one every other month. One out of 300</p> <p>17 to 400. It's pretty low.</p> <p>18 Q. That's related to transvaginal</p> <p>19 mesh complications generally speaking?</p> <p>20 A. Yeah.</p> <p>21 Q. Have you ever treated a patient</p> <p>22 with mesh that --</p> <p>23 MR. DeGREEFF: Strike that.</p> <p>24 Q. Have you ever -- well, yeah.</p> | <p style="text-align: right;">Page 261</p> <p>1 the mesh will come upon itself and have</p> <p>2 some folding. I've seen folding on a mesh</p> <p>3 failure because the attachment points have</p> <p>4 released, but I don't see curling and</p> <p>5 roping and what those things are that are</p> <p>6 described. I don't see them.</p> <p>7 Q. You've never seen any of those</p> <p>8 with regard to mesh slings?</p> <p>9 A. I've seen mesh folded on itself</p> <p>10 when there was a prolapse failure. So the</p> <p>11 mesh that was attached got released and it</p> <p>12 came back upon itself and folded.</p> <p>13 Q. I'm talking about mesh slings</p> <p>14 now.</p> <p>15 You're never seen a mesh sling</p> <p>16 that was roped or curled or frayed or</p> <p>17 anything?</p> <p>18 A. I don't know if you consider</p> <p>19 roping. When a sling is tight and you're</p> <p>20 going to release it, when you see that</p> <p>21 patient and it's tight and you go and look</p> <p>22 at -- and you release it, it looks a</p> <p>23 little narrower. I don't know if that's</p> <p>24 roping or curling. It does look a little</p> |

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| <p style="text-align: right;">Page 262</p> <p>1 narrower when it -- when it -- when the 2 tissue contracts and the sling contracts 3 with it for whatever reason for that 4 patient and the small fraction that end up 5 too tight and you have to go back, it 6 looks a little slimmer. 7 Q. Well, that's contraction of the 8 mesh. 9 Correct? 10 A. I don't know that it's 11 contracture. The mesh looks smaller. 12 Q. So you're saying when it 13 contracts and it gets under greater 14 tension, it looks thinner? 15 A. I don't know if it's an 16 inflammatory response that encases it. I 17 don't know if it's a tissue response. I 18 don't think we have studied that. And to 19 know what I'm referring to what's 20 happening at that point. It just looks a 21 little slimmer. 22 Q. But you've seen mesh slings that 23 have changed shape, that look slimmer. 24 True?</p> | <p style="text-align: right;">Page 264</p> <p>1 Q. It is challenging to remove all 2 of the mesh from a woman who's suffering 3 complications. 4 Is that a true statement? 5 A. There's some dissections that 6 are more difficult than others, but I 7 don't consider it to be an extremely 8 difficult procedure. 9 Q. For example, you know that 10 there's -- with the TVT-O product, you can 11 never safely removal all of the mesh from 12 inside a woman once it's implanted. 13 Right? 14 A. I agree. 15 Q. Okay. 16 A. The problem you're having, and 17 to clarify that disagreement, is that 18 there are surgeons who are taking out mesh 19 and they really only have the training to 20 take it out from the middle of the vagina 21 as far out laterally as they can reach, 22 and then there are surgeons who know how 23 to get behind the pubic bone and get 24 what's behind the pubic bone and get</p> |
| <p style="text-align: right;">Page 263</p> <p>1 A. When I take out patients that 2 have obstructions, they look a little 3 slimmer under the urethra. 4 Q. In your experience removing the 5 TVT products, were you able to remove all 6 of the mesh? 7 A. There are times where you decide 8 that you need to remove all the mesh and 9 times when you decide you don't need to. 10 When I decide a patient needs it 11 to be removed, I have removed all of it. 12 Q. You agree that physicians are 13 often unable to remove all the mesh? 14 A. It depends on their training. 15 The patient having a revision is best off 16 with someone with extensive experience in 17 handling this. 18 Q. Well, there are times when it's 19 just not -- when you're just not able to 20 remove all of the mesh. 21 True? 22 A. I have never had a case where I 23 couldn't remove the sling in totality when 24 I needed to.</p> | <p style="text-align: right;">Page 265</p> <p>1 what's wrapping around the descending 2 pubic ramus. 3 I've had obturators that were 4 taken out in totality several times. 5 Q. You had some that you couldn't 6 take out in totality? 7 A. No. 8 Q. Okay. 9 A. Now, microscopically, do I know 10 that there's nothing there, it seemed to 11 us that there was nothing more there. A 12 continuous band of ribbon. 13 Q. Doctor, have you ever been 14 employed by a medical device company? 15 A. As a consultant, not on a 16 payroll. 17 Q. I understand the consultant. 18 I'm saying have you ever been an 19 actual employee of a medical device 20 company? 21 A. No. 22 Q. You have been a consultant for a 23 medical device company. 24 Correct?</p> |

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| <p style="text-align: right;">Page 266</p> <p>1 A. Yes.</p> <p>2 Q. Which ones?</p> <p>3 A. The Laurus Corporation, Boston</p> <p>4 Scientific, Ethicon, Caldera.</p> <p>5 Q. What about Asera?</p> <p>6 A. No.</p> <p>7 Q. You've never been a consultant</p> <p>8 for Asera?</p> <p>9 A. When AMS was around, I had a</p> <p>10 couple, very few. So very briefly you</p> <p>11 could add it to the list, American Medical</p> <p>12 Systems.</p> <p>13 Asera, no.</p> <p>14 Q. Okay.</p> <p>15 A. Do they go by another name?</p> <p>16 Q. Not that I know of.</p> <p>17 A. No.</p> <p>18 Q. When did you start working for</p> <p>19 Caldera? I guess start consulting for</p> <p>20 Caldera?</p> <p>21 A. About five, six years ago.</p> <p>22 Q. So 2013, 2014? Something like</p> <p>23 that?</p> <p>24 A. About that.</p> | <p style="text-align: right;">Page 268</p> <p>1 We talked about what's unique</p> <p>2 about their trocar delivery flexibility</p> <p>3 and what could be added to that to</p> <p>4 continue to improve the flexibility</p> <p>5 options for patients. For instance, took</p> <p>6 the obturator trocars and said, you know,</p> <p>7 every woman's not the same size. Let's</p> <p>8 make different sizes. So there are some</p> <p>9 measurements we can use different sizes.</p> <p>10 So we've done a lot of different</p> <p>11 things that are tweaking things. Some</p> <p>12 have been adopted. Some are in the</p> <p>13 thought process. Some have been rejected.</p> <p>14 Q. So, were you essentially -- were</p> <p>15 you helping them with product design, or</p> <p>16 were you helping them with research and</p> <p>17 development?</p> <p>18 I mean, do you know how were you</p> <p>19 classified there?</p> <p>20 A. It really is research and</p> <p>21 development. It's trying to decide on new</p> <p>22 products and how to alter products to</p> <p>23 improve them.</p> <p>24 Q. Were you working on sling</p> |
| <p style="text-align: right;">Page 267</p> <p>1 Q. What did Caldera have you doing?</p> <p>2 A. Well, as I said, we got involved</p> <p>3 in them first in a non -- I got involved</p> <p>4 with them first in a non-consulting way.</p> <p>5 I liked their set of mesh kits, their</p> <p>6 ability to do everything in one kit, less</p> <p>7 expense and flexibility of the kit. So</p> <p>8 they're a small company. And I said, you</p> <p>9 know, I like to do design innovation. Can</p> <p>10 we take a look at your products and talk</p> <p>11 about what can be improved.</p> <p>12 So, if you take a look -- not</p> <p>13 that you would take a look to do their</p> <p>14 history, you'll see that Caldera now has a</p> <p>15 blue sheathe covered narrow sling, which</p> <p>16 was my original wish back with Gynecare</p> <p>17 and Boston Scientific.</p> <p>18 We -- they wanted to be also</p> <p>19 involved in the abdominal sacral</p> <p>20 suspension market. We talked about the</p> <p>21 weight and veracity of their mesh and how</p> <p>22 it handled and how it might be marked and</p> <p>23 colored and helped them develop the mesh</p> <p>24 for sacral suspension.</p> | <p style="text-align: right;">Page 269</p> <p>1 products?</p> <p>2 A. Sling and mesh products for</p> <p>3 sacral suspension.</p> <p>4 Q. And what were your -- what did</p> <p>5 you tell them about the weight of their</p> <p>6 mesh? You mentioned that as one of the</p> <p>7 things you were talking to them about.</p> <p>8 A. I said there seems to be, you</p> <p>9 know, across the slings -- across the very</p> <p>10 popular area of abdominal sacral</p> <p>11 suspensions is a huge broad area of stuff</p> <p>12 that's really, really lithe, that I</p> <p>13 thought was too lithe to things that were</p> <p>14 really stiff, and I thought their mesh</p> <p>15 handled well and was within the realm of</p> <p>16 acceptable weight and handling and I liked</p> <p>17 it.</p> <p>18 MS. GERSTEL: Could I just note</p> <p>19 for the record I don't know the extent</p> <p>20 to which any work that Dr. Lind did</p> <p>21 with any company is confidential.</p> <p>22 He's obviously taken on oath to tell</p> <p>23 the truth. I don't think I'm in a</p> <p>24 position to direct him not to answer</p> |

| Page 270 | Page 272 |
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| <p>1 any of those questions, but I also 2 don't know if we might need to seek 3 that some of this testimony be kept 4 confidential.</p> <p>5 I just want to say that for the 6 record. I'm just not sure. I just 7 want to state for the record I might 8 need to explore that after this 9 deposition. I'm not going to direct 10 him not to answer the question.</p> <p>11 MR. DeGREEFF: I mean, if you 12 want to move to have it sealed or 13 something, we may agree to that. I 14 just don't know what it is. If 15 there's some reason for that, then 16 yeah, we can talk about it.</p> <p>17 MS. GERSTEL: All right.</p> <p>18 BY MR. DeGREEFF:</p> <p>19 Q. So, what were the improvements 20 that you suggested to slings?</p> <p>21 A. For Caldera?</p> <p>22 Q. Yeah. I mean, you told me that 23 you were looking at ways to improve, kind 24 of, the slings that were currently on the</p> | <p>1 Q. So, basically 2013 to 2014 to 2 present you've been consulting for 3 Caldera?</p> <p>4 A. Yes.</p> <p>5 Q. How much are you being paid by 6 Caldera? Is there some sort of a yearly 7 consulting rate or something like that?</p> <p>8 A. It's an hourly rate. Just based 9 on à la carte services given.</p> <p>10 Q. What is your hourly rate with 11 them?</p> <p>12 A. Four hundred an hour.</p> <p>13 Q. How many hours a year since 2013 14 or 2014 do you think you've spent working 15 with Caldera?</p> <p>16 A. It varies. You know, if we're 17 in the middle of a product that they've 18 bought into, it could be 50 hours in a 19 year.</p> <p>20 Last year was only seven or 21 eight hours. So it varies quite a bit.</p> <p>22 Q. Are you aware of multiple years 23 working for them where you made more than 24 \$20,000?</p> |
| Page 271 | Page 273 |
| <p>1 market.</p> <p>2 What were some of your suggested 3 improvements?</p> <p>4 A. Well, the ones that are already 5 out there are ideas that I am holding 6 confidential. They haven't been put out 7 there yet.</p> <p>8 They adopted some things that 9 were already there with other slings which 10 was the narrow trocar and a colored 11 sheathe that could be identified. So 12 those aren't hidden or protected ideas. 13 They're -- there are some ideas on the 14 table about how to, one, make the sling 15 passage more comfortable in the 16 postoperative setting for pain; and two, 17 to identify an inadvertent pass in the 18 bladder that you might miss.</p> <p>19 Q. Anything about the mesh material 20 itself?</p> <p>21 A. No.</p> <p>22 Q. Are you still consulting for 23 Caldera?</p> <p>24 A. Yes.</p> | <p>1 A. Maybe two.</p> <p>2 Q. How far do you think you've been 3 paid by Caldera since you started working 4 for them?</p> <p>5 A. Fifty. 50,000.</p> <p>6 Q. You use Caldera slings. 7 Right?</p> <p>8 A. I do.</p> <p>9 Q. Is the Desara your sling of 10 choice?</p> <p>11 MS. GERSTEL: Object to form.</p> <p>12 A. It's the one I use most 13 commonly.</p> <p>14 Q. What percentage of the time do 15 you use the Desara?</p> <p>16 A. 75 percent.</p> <p>17 Q. What percentage of the time do 18 you use one of the Ethicon TVT slings?</p> <p>19 A. Ten percent.</p> <p>20 Q. And what are the other products 21 you use? The other sling products you 22 use?</p> <p>23 A. I use Boston Scientific, Caldera 24 and the Exact.</p> |

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1 Q. So, you would use the BSC you
2 use, is that the Advantage Fit?

3 A. Yes.

4 Q. What are the differences between
5 the Desara and the TVT slings?

6 A. Well, the meshes are different.
7 The shape of the trocars are similar. The
8 pathways are similar. The Caldera is
9 reusable trocars and comes with the
10 ability to change direction, size and
11 shape of your trocars. The Caldera for
12 the obturator has inside-out and
13 outside-in.

14 Those are the major -- those are
15 the differences I can think of.

16 Q. How are the meshes different
17 between the TVT slings and the Caldera?

18 A. Well, the present mesh I like to
19 use for Ethicon is the TVT-Exact. So it's
20 laser-cut and the Caldera is
21 mechanically-cut.

22 Q. Any other differences?

23 A. I'm sure there's a chart I've
24 seen where their porosity and pore size

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1 have some other differences. So they do,
2 you know, on a -- on a chart of mechanical
3 properties they differ.

4 Q. The Desara is larger pore mesh
5 than the TVT-Exact.

6 True?

7 A. I think we had that one before,
8 and I thought we had -- I thought that was
9 the other way around, but I could be
10 mistaken.

11 Q. Is the Desara more resistant to
12 deformation than the TVT sling products?

13 A. I'm not aware of that being
14 studied officially or by myself. I don't
15 notice a difference clinically.

16 Q. So you're not aware of
17 literature that says it is?

18 A. I don't know if one of the
19 mechanical studies that pulled on each
20 thing described it in a certain way.

21 I do remember in that same
22 article that has the chart that says the
23 pore sizes and the weight, I think it also
24 discussed what happened to them under

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1 stress and it probably shows different
2 properties. I don't remember what it
3 shows.

4 It behaves the same in the
5 patient for me.

6 Q. Are you aware that Caldera makes
7 the claim that their product, their TVT
8 product is -- that the Desara is more
9 resistant to deformation than the TVT
10 products?

11 A. I wasn't aware of that.

12 Q. So you don't have any idea what
13 that claim is based on?

14 A. I do not.

15 Q. Do you have any reason to
16 disagree with Caldera?

17 A. I would just ask them to show me
18 what it's based on.

19 Q. Do you disagree with them or no?

20 A. I don't have the knowledge to
21 agree or disagree.

22 Q. So, you use the Desara because
23 it's --

24 MR. DeGREEFF: Strike that.

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1 Q. So the Desara is a
2 mechanical-cut mesh.

3 Is that correct?

4 A. Yes.

5 Q. The TVT-Exact is laser-cut.
6 True?

7 A. Yes.

8 Q. The TVT-Abbrevio is laser-cut?

9 A. Yes.

10 Q. And the TVT-O has both laser-cut
11 and mechanical-cut options.

12 Right?

13 A. Yes.

14 Q. You said you worked for Boston
15 Scientific as a consultant.

16 Is that true?

17 A. Yes.

18 Q. When did you start working for
19 Boston Scientific as a consultant?

20 A. That was a ways back.

21 So, they sold the device that I
22 helped make was sold in 1996 or '97. So
23 1998 they asked me to come on since I had
24 helped to make the device together, and we

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| <p style="text-align: right;">Page 278</p> <p>1 started -- I started doing that study 2 about the using that device to make first 3 it was in a scientific role doing studies, 4 the two studies for the sacrospinous 5 suspension and for the mini incisional 6 Burch procedure. And as that relationship 7 grew, we started talking about, you know, 8 how they could improve their pelvic floor 9 products. 10 I had gone to Ethicon, as the 11 theme continues, I had gone to Ethicon 12 about making the needle smaller and they 13 didn't want to. So we made the Advantage 14 Fit together. 15 Q. Okay. And, so, that would have 16 been like 1996 that you started consulting 17 with BSC? 18 A. '96 or '97 is when they sold the 19 device. So my consulting would have 20 started in like '98. Somewhere in that 21 range. 22 Q. Okay. So you were not 23 consulting with them before they sold the 24 device?</p> | <p style="text-align: right;">Page 280</p> <p>1 development. They asked for my opinion on 2 some of the vaginal mesh products when 3 they started making those. 4 Q. So it sounds like they were 5 asking you for input on just kind of the 6 use of the device as well as some R&D 7 aspect. 8 Is that fair? 9 A. Product development and 10 teaching. 11 Q. And you currently use the BSC 12 Advantage. 13 Right? 14 A. To a small degree. 15 Q. And were you being paid by BSC 16 as a consultant for that 17-year span, I'm 17 assuming? 18 A. Yes. 19 Q. How much do you think you were 20 paid in that 17 years by BSC? 21 A. That wasn't high volume per 22 year. I mean, ten a year, approximate. 23 Q. Ten thousand a year? 24 A. Ten thousand a year if I was</p> |
| <p style="text-align: right;">Page 279</p> <p>1 A. Correct. 2 Q. So 1998 until when did you stop 3 consulting with BSC? 4 A. Four years ago. 5 Q. So 2015-ish? Is that correct? 6 A. Yeah, around that time. 7 It's all approximates. 8 Q. It sounds like were you doing 9 R&D type work for them, or was there some 10 other aspect of it? 11 A. I was teaching in labs trying to 12 teach people good -- the best technique, 13 or at least my best technique for placing 14 slings and doing the sacrospinous 15 suspension. So a lot of lab work 16 teaching. 17 I was working on R&D for the 18 slim sling. Wasn't that extensive. We 19 were just making the needle narrow and 20 putting the tube on it. You know, as far 21 as a change, it's a significant change in 22 a product. 23 They asked for my opinion on 24 some of the -- I was involved in the</p> | <p style="text-align: right;">Page 281</p> <p>1 involved in a project. Maybe it was 20 on 2 a year where we were more involved in 3 focusing on something. 4 Q. So, over 15 years, maybe 150 to 5 200,000? 6 A. 15 years, yeah, somewhere in 7 that range. 8 Q. What are the differences between 9 the BSC Advantage sling and the TVT 10 products? 11 MS. GERSTEL: Objection; asked 12 and answered, I think. 13 THE WITNESS: Yeah, it was? 14 I'll answer it. 15 A. So, the Boston Sci slings are 16 all laser-cut. The central portion of the 17 sling is also heat-treated potentially to 18 make it a little more robust in that area. 19 So it is stiffer for sure. 20 Other than that, the TVT-Exact 21 and the TVT have a very similar shape, a 22 very similar angle. You know, when I was 23 consulting with Boston Sci, we were 24 basically making a TVT that was skinnier.</p> |

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| <p style="text-align: right;">Page 282</p> <p>1 So the shape was similar. The arc of the 2 needle is similar. You know, the porosity 3 of the mesh is slightly different. 4 I can't tell you what it is, but 5 it's all within the type one mesh 6 characteristics. 7 Those are the major differences. 8 Q. You said you did some consulting 9 for AMS. 10 Is that right? 11 A. Very little. 12 Q. When did you start that? 13 A. It was in the vaginal mesh era. 14 They asked me to come up and do one or two 15 labs to see what I thought of their 16 vaginal mesh. It was a one or two gig 17 thing. 18 Q. What did they pay you for doing 19 those labs? 20 A. I think 3500. 21 Q. Total or each? 22 A. Each one. 23 That includes a trip to 24 Minnesota in the winter. So you could say</p> | <p style="text-align: right;">Page 284</p> <p>1 things and I said this one may be a tough 2 one, and they ended up closing that case 3 before I ever lent the opinion. 4 So, there are discussions 5 sometimes where I tell them that, you 6 know, this case looks a little difficult. 7 MS. GERSTEL: I'll just state 8 not to reveal any discussions with 9 counsel. 10 THE WITNESS: Right. 11 BY MR. DeGREEFF: 12 Q. So they settled that case before 13 you had to say no, basically? 14 A. I didn't say that I said no. I 15 was evaluating it, but they settled the 16 case before I got deeper. 17 Q. So the answer is no, you've 18 never told them no on any case they've 19 asked you to be an expert witness on? 20 A. At this point, no. 21 Q. In all the case-specific reports 22 you've done for Ethicon, you've ultimately 23 concluded that the product, i.e. the mesh 24 manufactured by Ethicon, was not the cause</p> |
| <p style="text-align: right;">Page 283</p> <p>1 I paid them. 2 Q. So roughly seven grand total 3 with them? 4 A. Yeah. 5 Q. Have you done anything with them 6 since then? 7 A. No. 8 Q. How many -- since you've been 9 acting as an expert witness for Ethicon, I 10 believe you said you've given your general 11 opinion and then there's been four or five 12 case-specifics. 13 True? 14 A. Yes. 15 Q. Have you ever told Ethicon no 16 when they came to you and asked you to 17 give an opinion on a specific -- in favor 18 of a specific case? 19 A. Of a case? 20 I think we had one where, you 21 know, the materials were sent and then 22 they said look at the other ones first 23 because we're working on this. I glanced 24 at the case and looked at some of the key</p> | <p style="text-align: right;">Page 285</p> <p>1 of the plaintiff's complications. 2 True? 3 MS. GERSTEL: Object to form. 4 A. Yes. 5 Q. Have you ever given the opinion 6 that one of Ethicon's mesh products caused 7 a woman's pain or other complications? 8 A. Well, the product used by a 9 surgeon and the use of the product not 10 being used correctly is different than the 11 product itself causing the damage. So I 12 never have thought that the product itself 13 caused the damage. 14 Q. But you've blamed the doctor in 15 some of them, in some of your -- 16 A. I didn't blame the doctor. I 17 assessed the materials and assessed that 18 the technique issues were problematic. 19 Q. So you blamed the doctor 20 ultimately and said that it was the 21 doctor's fault? 22 MS. GERSTEL: Object to form. 23 24 BY MR. DeGREEFF:</p> |

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| <p style="text-align: right;">Page 286</p> <p>1 Q. True?</p> <p>2 A. Sometimes it was a technique</p> <p>3 problem. Sometimes it was a concomitant</p> <p>4 procedure and it may not be the doctor's</p> <p>5 fault. If you do a posterior repair, you</p> <p>6 can have dyspareunia and it doesn't mean</p> <p>7 the doctor was faulty.</p> <p>8 It's a known complication of</p> <p>9 other gynecologic procedures that happen</p> <p>10 concurrently with the mesh procedure. So</p> <p>11 it's not necessarily that I'm blaming the</p> <p>12 doctor.</p> <p>13 Q. Have you ever given the opinion</p> <p>14 that any mesh product caused a woman's</p> <p>15 injury?</p> <p>16 A. I've never given the opinion</p> <p>17 that a mesh product separate from the</p> <p>18 procedure caused an injury.</p> <p>19 Q. You've given the opinion that</p> <p>20 the procedure was somehow done wrong and</p> <p>21 that was the cause?</p> <p>22 MS. GERSTEL: Object to form.</p> <p>23 A. If there's a problem with a</p> <p>24 procedure when you're using mesh, it can</p> | <p style="text-align: right;">Page 288</p> <p>1 A. Approximately that.</p> <p>2 Q. You consulted with them until</p> <p>3 roughly 2012.</p> <p>4 Right?</p> <p>5 A. Well, I think there was -- in</p> <p>6 2012, I think that might have been the --</p> <p>7 there was a big gap. So yes, from a time</p> <p>8 frame, you go to 2012. But I think if</p> <p>9 you've got the records from when I worked</p> <p>10 for them, there was a pretty big gap. I</p> <p>11 was not doing a lot of Gynecare work for a</p> <p>12 few years and then they asked me and asked</p> <p>13 me if I would come take a look -- I think</p> <p>14 there's one data point that's making that</p> <p>15 look extended. So it may be five to eight</p> <p>16 years and not twelve years just because I</p> <p>17 think that 2012 is an outlier. But you'd</p> <p>18 have to look at -- I know you have the</p> <p>19 records of everything that I've done. So</p> <p>20 we'd have to look more closely at it.</p> <p>21 Q. So we're looking at eight to</p> <p>22 eleven years where you were either a</p> <p>23 consultant or an expert for Ethicon in the</p> <p>24 last 17.</p> |
| <p style="text-align: right;">Page 287</p> <p>1 lead to complications. It wouldn't happen</p> <p>2 if the procedure was done right.</p> <p>3 The mesh characteristics I don't</p> <p>4 think would have harmed the woman.</p> <p>5 Q. Do you have any understanding</p> <p>6 why you were chosen as an expert witness</p> <p>7 for Ethicon in this litigation?</p> <p>8 A. I've got a good reputation in</p> <p>9 the field for 23 years. I do good</p> <p>10 clinical work. I publish. I'm easy to</p> <p>11 get along with.</p> <p>12 Q. And you've been an Ethicon</p> <p>13 consultant or expert witness for 17 years</p> <p>14 now.</p> <p>15 Is that right?</p> <p>16 A. Well, the expert witness now is</p> <p>17 for about three, three-and-a-half years.</p> <p>18 And the Ethicon consulting was from, I</p> <p>19 would have to look back at the transcript.</p> <p>20 It was probably five to ten years.</p> <p>21 They're not continuous, but --</p> <p>22 Q. Well, you started in 2002 as a</p> <p>23 consultant for them.</p> <p>24 Right?</p> | <p style="text-align: right;">Page 289</p> <p>1 Right?</p> <p>2 A. Sounds about right.</p> <p>3 Q. And you've been using their</p> <p>4 product since 2000?</p> <p>5 A. Yes.</p> <p>6 MR. DeGREEFF: We can take a</p> <p>7 break.</p> <p>8 (Recess taken.)</p> <p>9 BY MR. DeGREEFF:</p> <p>10 Q. Sir, do you remember doing any</p> <p>11 work for Astellas?</p> <p>12 A. Yes.</p> <p>13 Q. And what was that?</p> <p>14 A. A pharmaceutical company made a</p> <p>15 drug for the overactive bladder.</p> <p>16 Q. Do you do some consulting for</p> <p>17 them, it looks like?</p> <p>18 A. Yes.</p> <p>19 Q. And when did you do that?</p> <p>20 A. I don't know the exact years.</p> <p>21 It would probably be like three years ago</p> <p>22 to six years ago, so.</p> <p>23 Q. 2013 to 2016?</p> <p>24 A. Yeah.</p> |

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1 Q. Do you have any idea how much
2 you were paid by them?
3 A. Maybe 5,000 a year.
4 Q. So maybe 15 total?
5 A. Yeah.
6 Q. I want to discuss, you told me
7 earlier you were paid about 50,000 by
8 Caldera.
9 Do you remember that?
10 A. Yes.
11 Q. I want to talk to you about
12 that.
13 Do you remember being paid \$6500
14 by Caldera in 2013?
15 A. I wouldn't be able to recall the
16 yearly in this meeting.
17 Q. Do you know what the open
18 payments data is on the CMS website?
19 A. I assume it's a public record of
20 what I've been paid for various
21 activities.
22 Q. Right.
23 If Caldera reported that they
24 paid you \$6,500 in 2013, would you

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1 disagree with that?
2 A. I would have to check my
3 records. I don't know that those records
4 are -- I do know that some of the online
5 records of what I've been allegedly paid
6 were wrong.
7 So, I would say that we are
8 discussing consulting years ago, ranges
9 and payments, and I would suggest that I
10 come up with the actual payments from
11 payroll would be something I'd like to do.
12 Q. So you want to go chase down for
13 me all of your accounting records for
14 everything you've received from all of
15 these pharmaceutical companies?
16 MS. GERSTEL: Object to form.
17 A. Well, I don't know we're -- you
18 know, we're guessing at a lot of
19 activities with a lot of companies across
20 20 years. It seems like the -- I don't
21 know how on target they would be.
22 I do know the online stuff, I
23 looked one time it was off by a digit, and
24 we do have to contact them. There was one

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1 time I had to contact them to make it
2 corrected.
3 Q. Well, in 2014, do you remember
4 being paid \$25,000 by Caldera?
5 A. I don't remember the yearly
6 number.
7 Q. Does that sound inaccurate to
8 you?
9 A. There was a year or two where I
10 was doing a lot of work.
11 Q. In 2015 do you remember being
12 paid \$25,000 again by Caldera?
13 A. I don't remember the number, but
14 it's plausible. As I said, there were a
15 couple of years where it was heavy.
16 Q. In 2016, do you recall being
17 paid \$18,600 by Caldera?
18 A. It's certainly possible.
19 Q. In 2017, do you recall being
20 paid \$8,000 by Caldera?
21 A. That sounds familiar.
22 Q. So, I get more like \$80,000 paid
23 to you by Caldera.
24 Does that sound accurate to you?

Page 293

1 A. It sounds like the records you
2 have show that.
3 Q. Do you disagree with that? Does
4 that sound out of line?
5 A. It may be right. It may be plus
6 or minus 20.
7 I will go to their accounting
8 and ask them.
9 It doesn't sound erroneous.
10 MR. DeGREEFF: Sir, I'm going to
11 hand you what I'm going to mark as
12 Deposition Exhibit 10.
13 (Lind Exhibit 10, Consulting
14 Agreement dated as of January 3, 2002
15 between Lawrence Lind, M.D. and
16 Ethicon, Inc., Bates No.
17 ETH.MESH.16009738 to 16009743, was
18 marked for identification, as of this
19 date.)
20 BY MR. DeGREEFF:
21 Q. Sir, does this appear to be a
22 consulting agreement between you and
23 Ethicon?
24 A. Looks like it.

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| <p style="text-align: right;">Page 294</p> <p>1 Q. What is the date of that?</p> <p>2 A. 2002.</p> <p>3 Q. January 3rd of 2002?</p> <p>4 A. Yep.</p> <p>5 Q. Does that sound familiar as</p> <p>6 about the time you started working for</p> <p>7 Ethicon as a consultant?</p> <p>8 A. It's about where I thought it</p> <p>9 was.</p> <p>10 And it looks clearly it's a</p> <p>11 document that's real.</p> <p>12 Q. If you look at under Section 1</p> <p>13 "Consultant," my only question is with</p> <p>14 that paragraph is there's a spot in it</p> <p>15 that says: Keep records of hours worked</p> <p>16 and cost of materials used.</p> <p>17 Was that something that you</p> <p>18 would have done?</p> <p>19 A. You know, the consulting for</p> <p>20 them was not at home working on documents.</p> <p>21 They would call me to do a lab. It was a</p> <p>22 half-day lab. They'd pay \$3,000 and it</p> <p>23 was a one-at-a-time thing.</p> <p>24 So, there really wasn't any</p> | <p style="text-align: right;">Page 296</p> <p>1 that one day.</p> <p>2 So, there were not -- there</p> <p>3 aren't records, I don't have a spreadsheet</p> <p>4 or a record of the hours worked.</p> <p>5 Q. Okay.</p> <p>6 I don't see that I ever asked</p> <p>7 you that, but how much do you think you</p> <p>8 were paid by Ethicon as a consultant? Not</p> <p>9 as a expert witness, but as a consultant?</p> <p>10 A. I don't know. It started a long</p> <p>11 time ago. Spanned a long period. There</p> <p>12 were periods with big gaps where I didn't</p> <p>13 do much at all, and there were periods</p> <p>14 where I did a lot.</p> <p>15 So I really cannot conjure a</p> <p>16 guess. I don't know if it's 20,000 or a</p> <p>17 hundred thousand. I really don't know.</p> <p>18 Q. And who would know that answer,</p> <p>19 if not you?</p> <p>20 A. I don't know if Ethicon has the</p> <p>21 records or if their accounting goes back</p> <p>22 that far.</p> <p>23 Q. So, if you look at page 3 of</p> <p>24 this agreement, the term of the agreement</p> |
| <p style="text-align: right;">Page 295</p> <p>1 recordkeeping. You'd go. You'd submit</p> <p>2 one at a time. It wasn't a kind of like a</p> <p>3 cumulative work that was being added that</p> <p>4 you recorded.</p> <p>5 So, I would say I kept records,</p> <p>6 but it was one at a time, and once you did</p> <p>7 it, I didn't keep track after that.</p> <p>8 Q. So I guess my question is are</p> <p>9 there any records in existence that would</p> <p>10 have a detail of the hours worked under</p> <p>11 this consulting agreement?</p> <p>12 A. I don't have it, and I don't</p> <p>13 know if Ethicon would have it.</p> <p>14 Q. Would that have been something</p> <p>15 you would have submitted to Ethicon?</p> <p>16 A. As I said, it was a</p> <p>17 one-day-at-a-time type of working</p> <p>18 agreement. So even though it's</p> <p>19 instructing to keep hours, I think that's</p> <p>20 requesting to kind of keep the accounting</p> <p>21 in order. The way I worked, it was just</p> <p>22 a, you know, once every few weeks or few</p> <p>23 months they asked me to come to do</p> <p>24 something and I went and I submitted for</p> | <p style="text-align: right;">Page 297</p> <p>1 commenced on January 3rd of 2002 and seems</p> <p>2 to have terminated on February 28th of</p> <p>3 2002.</p> <p>4 Do you have any idea why it was</p> <p>5 so short?</p> <p>6 A. You know, I'd have to read the</p> <p>7 whole agreement.</p> <p>8 As I recall, there was a time</p> <p>9 where anyone -- the contracts they had had</p> <p>10 things that said you couldn't work with</p> <p>11 anyone else. So, I said well, you know, I</p> <p>12 have ideas I'm working on and you're</p> <p>13 rejecting them. So, I don't know if</p> <p>14 that's why.</p> <p>15 So this may have been made</p> <p>16 because I didn't agree to some of the</p> <p>17 terms of their long-term agreement, but</p> <p>18 they wanted me to come for this one</p> <p>19 session, so we made a short-term contract.</p> <p>20 So it does seem odd.</p> <p>21 Q. I think the situation you're</p> <p>22 talking about was in 2010.</p> <p>23 And maybe if you turn to page 4</p> <p>24 of Exhibit 10, that will kind of clarify</p> |

| Page 298 | Page 300 |
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| <p>1 it for you. If you look at 6 and 7, 2 paragraph 6 and 7. 3 A. Yeah, it looks like it's an 4 invitation to go to one session, abdominal 5 guides training session. 6 Q. That's what I was going to ask. 7 So, it looks like they were 8 paying you \$3,000 for coming to a 9 abdominal guides training session? 10 A. Right. 11 Q. Did you get that \$3,000 just to 12 show up, or did you have to teach? 13 A. I was definitely teaching 14 abdominal guides. They weren't -- I would 15 be one of the people teaching it, not 16 learning how to do it. 17 Q. How long was that training 18 session? 19 A. They usually were a half-day to 20 six hours. Four to six hours. 21 Q. Where did those take place? 22 A. They were in a number of 23 locations. It was various places that had 24 access to cadavers. So I don't know where</p> | <p>1 you what I've marked as Deposition 2 Exhibit 11. 3 (Lind Exhibit 11, Clinical Study 4 Agreement between Gynecare and North 5 Shore University Hospital, Bates No. 6 ETH.MESH.00412092 to 00412098, was 7 marked for identification, as of this 8 date.) 9 BY MR. DeGREEFF: 10 Q. Can you tell me what that is? 11 A. Clinical study agreement. 12 Q. And the term of that agreement 13 is April 4th, 2002 through the end of 14 June, through June 30th of 2004. 15 Correct? 16 A. Right. 17 Q. This was between Gynecare, which 18 is a division of Ethicon, correct? 19 A. Yes. 20 Q. And your institution with you 21 and Dr. Garely designated as the, looks 22 like, the primary people in charge of 23 this? 24 A. Investigators.</p> |
| Page 299 | Page 301 |
| <p>1 it took place, but the closest it would be 2 in 2000 -- it wasn't on Long Island until 3 later in our agreements because we didn't 4 have cadaver labs. So it would either be 5 Manhattan, New Jersey. 6 Q. Somewhere in the New York 7 metropolitan area? 8 A. Yeah. I wasn't flying for this. 9 Q. And they were essentially paying 10 you \$3,000 for a half-day participation? 11 A. Well, as I said, it would be 12 four to six hours, plus the transportation 13 and time. So, you know, door to door, it 14 would certainly be more than eight hours. 15 Q. Did they pay you for your 16 transportation and hourly rate also? 17 A. They paid the amount and then 18 just incurred costs for transition. It 19 wasn't an hourly rate on top of that. 20 Q. So \$3,000 for roughly eight 21 hours. 22 Is that right? 23 A. Yeah. 24 MR. DeGREEFF: I'm going to hand</p> | <p>1 Q. Is that correct? 2 Who is Dr. Alan Garely? Do you 3 know him? 4 A. He was a previous partner in my 5 practice, and he now practices in 6 Manhattan and south shore of Long Island. 7 Q. Do you know him personally? 8 A. You know, I mean, we were 9 partners for three years. So I did know 10 him personally. We don't socialize at 11 present. 12 Q. Is he a good doctor? 13 A. He's a good surgeon. I don't 14 think -- again, I haven't seen him take 15 care of patients in 15 years. 16 Q. I mean, do you have any 17 criticisms of him as a physician? 18 MS. GERSTEL: Object to form. 19 A. He could get upset with someone, 20 and then it wasn't a good scene. 21 Q. Okay. That's not really him as 22 a surgeon. It sounds like maybe you -- 23 A. I haven't seen him in a 24 practicing situation for 15 years. So I</p> |

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| <p style="text-align: right;">Page 302</p> <p>1 really don't think I can say anything.</p> <p>2 Q. Okay.</p> <p>3 So, Dr. Garely was one of the</p> <p>4 investigators hired by Ethicon to do this</p> <p>5 clinical study agreement with you --</p> <p>6 A. Yes.</p> <p>7 Q. I mean to do this clinical study</p> <p>8 with you.</p> <p>9 Do you know when was the last</p> <p>10 time you spoke to Dr. Garely?</p> <p>11 A. A couple months ago.</p> <p>12 Q. Do you know whether he currently</p> <p>13 uses the TVT-O, TVT or TVT-Abbrevio?</p> <p>14 A. I don't.</p> <p>15 Q. Have you ever been provided with</p> <p>16 any of the testimony or documentation of</p> <p>17 what he told Ethicon about those devices?</p> <p>18 A. I think I saw one of his mesh</p> <p>19 reports. I don't think I saw a sling</p> <p>20 report.</p> <p>21 Q. So, as you sit here, do you have</p> <p>22 any idea what he told Ethicon about the</p> <p>23 TVT-O, TVT-E and TVT-Abbrevio?</p> <p>24 A. I don't.</p> | <p style="text-align: right;">Page 304</p> <p>1 Q. If you look at paragraph 1 where</p> <p>2 it says: Performance of study.</p> <p>3 As the principal investigator,</p> <p>4 you were to perform the study in</p> <p>5 accordance with the protocol.</p> <p>6 Right?</p> <p>7 A. Right.</p> <p>8 Q. Who determined the protocol?</p> <p>9 A. I would have to look at the</p> <p>10 protocol to comment on that. But I would</p> <p>11 say that any study I enrolled in, I would</p> <p>12 have to believe that it was a protocol</p> <p>13 that I agreed with. So there can be</p> <p>14 suggestions from a company as to what they</p> <p>15 might want to happen, but I would never</p> <p>16 have a -- subject my patients to any</p> <p>17 protocol that I didn't specifically take</p> <p>18 responsibility for if I was a principal</p> <p>19 investigator.</p> <p>20 Q. Well, Ethicon determined the</p> <p>21 protocol that was used.</p> <p>22 Right?</p> <p>23 A. I am ultimately responsible for</p> <p>24 the protocol that gets submitted to the</p> |
| <p style="text-align: right;">Page 303</p> <p>1 Q. Is it your understanding that</p> <p>2 Dr. Garely is now a plaintiff's expert in</p> <p>3 the transvaginal mesh litigation?</p> <p>4 A. I do understand that.</p> <p>5 Q. And you reviewed his report?</p> <p>6 A. I reviewed his mesh report.</p> <p>7 Q. When you say "his mesh report,"</p> <p>8 are you talking about with regard to the</p> <p>9 Prolift?</p> <p>10 A. Yes.</p> <p>11 Q. So, this is a former consultant,</p> <p>12 or I guess someone who is a former</p> <p>13 investigator on a study done by Ethicon</p> <p>14 who's now providing testimony for the</p> <p>15 women injured by Ethicon devices.</p> <p>16 Is that right?</p> <p>17 MS. GERSTEL: Object to form.</p> <p>18 A. Looks like he was a previous</p> <p>19 participant in this study and he is now a</p> <p>20 plaintiff's expert, as you described.</p> <p>21 Q. Well, plaintiff meaning the</p> <p>22 women who are claiming injuries.</p> <p>23 True?</p> <p>24 A. Yes.</p> | <p style="text-align: right;">Page 305</p> <p>1 IRB.</p> <p>2 Q. I understand.</p> <p>3 A. How much of the protocol was</p> <p>4 created by them and edited by me or</p> <p>5 created totally by me I don't think we can</p> <p>6 answer at this meeting.</p> <p>7 Q. If you look at paragraph 3</p> <p>8 "Financial Consideration and Payment</p> <p>9 Schedule."</p> <p>10 You see where I'm at?</p> <p>11 A. Mm-hm.</p> <p>12 Q. It says: The total price for</p> <p>13 the conduct and the completion of study as</p> <p>14 well as the payment schedule is outlined</p> <p>15 in Schedule B.</p> <p>16 Did I read that correctly?</p> <p>17 A. Yep.</p> <p>18 Q. Look at Schedule B, if you</p> <p>19 would. It's on page 6.</p> <p>20 Are you there?</p> <p>21 A. Yes.</p> <p>22 Q. It appears that the total</p> <p>23 payment being made by Ethicon is \$11,000.</p> <p>24 Is that correct?</p> |

| Page 306 | Page 308 |
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| <p>1 A. That's the planned -- that's the 2 budget for the -- for the study. Right. 3 How much was actually paid with 4 how many subjects, we don't know. This is 5 the schedule of payments ahead of time of 6 what would be paid. Each line item would 7 have to be carried out to be paid that. 8 It's not paid in advance, so. 9 Q. Okay. That's the projected 10 \$11,000 for the payment for the study? 11 A. Right. 12 Q. And this was between 2002 and 13 2004 that you were conducting this study? 14 A. Yes. 15 Q. So, the title of the study is "A 16 clinical assessment of patients undergoing 17 Gynecare TVT with abdominal guides for the 18 treatment of stress urinary incontinence." 19 Correct? 20 A. Right. 21 Q. And what was the ultimate goal 22 of the study? 23 A. You know, they had a retropubic 24 sling, the standard TVT that went from</p> | <p>1 between Gynecare and Lawrence Lind, 2 MD, Bates No. ETH.MESH.09464276 to 3 09464279, was marked for 4 identification, as of this date.) 5 BY MR. DeGREEFF: 6 Q. Can you tell me what that is? 7 A. It's a privacy agreement to 8 discuss intellectual property. 9 Q. It's actually better than that. 10 It's called a Secrecy Agreement. 11 Right? 12 A. That's how they titled it. 13 Q. And that's between you and 14 Gynecare. 15 Correct? 16 A. Right. 17 Q. And Gynecare is a part of 18 Ethicon? 19 A. Yes. 20 Q. I want to ask you a couple of 21 questions. First is in paragraph 1 on the 22 front page. 23 You see where I'm at? 24 A. Yep.</p> |
| Page 307 | Page 309 |
| <p>1 bottom up, from the vagina upward, and 2 there were a -- from the urology teachings 3 of slings of long ago, there's a different 4 way of passing a sling that started from 5 the top down, which a lot of urologists 6 favor. So the -- it was a design of an 7 instrument by Gynecare to try to add that 8 to their product line and to give those 9 who felt that that was a safer passage the 10 opportunity to go from the top down. 11 So, the purpose of this study 12 was to look at efficacy of safety of a 13 sling that went from the top down rather 14 than the bottom up. 15 Q. And what was the result? 16 A. I don't think it got off the 17 ground and got enough numbers for 18 enrollment, because I don't think I ever 19 saw a publication from it. 20 MR. DeGREEFF: Sir, I'm going to 21 hand you what's been marked as 22 Deposition Exhibit 12. 23 (Lind Exhibit 12, Secrecy 24 Agreement dated January 19, 2004</p> | <p>1 Q. It states that it's to determine 2 whether to enter into a mutually 3 attractive business arrangement. 4 Did I read that correctly? 5 A. I see it. 6 Q. What does that mean? What was 7 the mutually attractive business 8 arrangement that you were trying to decide 9 whether to enter into with Ethicon? 10 MS. GERSTEL: Object to form. 11 A. This is 2004. So this may have 12 been when I wanted to propose to them the 13 slim modification of the TVT. So I was 14 disclosing some personal information that 15 I didn't have intellectual property on, 16 but I had drawings. I had writings. I 17 had sealed documentation that I had come 18 up with this idea. 19 So, I don't know for sure, but I 20 think that this is a scenario to sit down 21 and talk about an idea that I had. And, 22 you know, usually in this situation, if a 23 company likes your idea, then they 24 purchase it from you and there's a</p> |

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| <p style="text-align: right;">Page 310</p> <p>1 business arrangement made. I've never had 2 one of those arrangements, but I'm 3 extrapolating. I can't say for certain 4 that's what we were doing here. But this 5 sounds like a scenario where I'm 6 presenting them with an idea and they're 7 going to decide whether there's something 8 mutually agreeable that would come out of 9 this.</p> <p>10 MS. GERSTEL: I'm just going to 11 place a late objection that that -- I 12 believe that that's a 13 mischaracterization of the document 14 and the agreement.</p> <p>15 BY MR. DeGREEFF:</p> <p>16 Q. So, would you have been asking 17 them to partner up on your idea? Is that 18 kind of what you were doing?</p> <p>19 MS. GERSTEL: Object to the 20 form.</p> <p>21 A. Well, when you have an idea, you 22 want to present it. And I'm not in a 23 position to take a idea and make it into a 24 sling. So you go to a reputable company</p> | <p style="text-align: right;">Page 312</p> <p>1 Did I read that correctly?</p> <p>2 A. Yeah.</p> <p>3 Q. So, you weren't even, under this 4 secrecy agreement, you weren't even 5 allowed to disclose that you had a 6 relationship with Ethicon.</p> <p>7 Is that what this says?</p> <p>8 A. It says that I would have to 9 tell them if I was telling someone else.</p> <p>10 Q. So, when you were offering your 11 patients the TVT sling devices, did you 12 disclose to them that you had a consulting 13 relationship with Ethicon and several 14 other sling manufacturers?</p> <p>15 A. I did and I do.</p> <p>16 Q. Did this prohibit you from doing 17 that?</p> <p>18 MS. GERSTEL: Object to the 19 form.</p> <p>20 A. No.</p> <p>21 Q. Why do you disclose your 22 consulting relationship with Ethicon and 23 other sling manufacturers to your 24 patients?</p> |
| <p style="text-align: right;">Page 311</p> <p>1 that's right now the leader in sling 2 products, and you bring your idea to them 3 to see whether they like it.</p> <p>4 So, partner up, you could call 5 it partner up or you could call it a 6 routine scenario where someone with an 7 idea brings an idea to a company and if 8 it's deemed valuable, there's a business 9 arrangement made to purchase the 10 intellectual property and there's a 11 financial arrangement made with them.</p> <p>12 Q. Well, if they're the leader 13 currently, then why didn't you go to them 14 with your current device? Why did you go 15 to BSC and Caldera instead?</p> <p>16 A. Because my relationships with 17 them are more current.</p> <p>18 Q. It states: The parties further 19 agree not to disclose the relationship 20 between the parties or the existence of 21 this agreement to any third party without 22 the consent of the other.</p> <p>23 And there's a three-year 24 effective date on that.</p> | <p style="text-align: right;">Page 313</p> <p>1 A. Because I want to make sure I 2 have a discussion that lets them know I 3 work towards betterment and improvement of 4 these products all the time. That means I 5 work with the companies. And there are 6 payments made sometimes for that 7 consulting work, and I don't want them to 8 discover that and feel that I hid 9 something that they would think was, you 10 know, financial motivation. I tell them 11 the relationship. I tell them why I use 12 the product, and I tell them why I'm 13 working with them.</p> <p>14 Q. Okay.</p> <p>15 A. Seems like the responsible thing 16 to do.</p> <p>17 Q. Right.</p> <p>18 Because being paid by somebody 19 can create a bias towards using a product. 20 Right?</p> <p>21 A. Correct.</p> <p>22 MR. DeGREEFF: I'm going to mark 23 for you Deposition Exhibit 13. 24 (Lind Exhibit 13, e-mail chain</p> |

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| <p style="text-align: right;">Page 314</p> <p>1 ending June 15, 2004, Bates No. 2 ETH.MESH.11003781 to 11003783, was 3 marked for identification, as of this 4 date.) 5 BY MR. DeGREEFF: 6 Q. So, I have handed you what 7 appears to be an exchange, an e-mail 8 exchange from it's the June of 2004 date 9 range. 10 Does that look accurate? 11 A. This is 2004 communications, 12 right. 13 Q. And if you look at the initial 14 two e-mails on the chain, meaning the 15 earliest in time, you are a recipient on, 16 I guess two of the three earliest you're a 17 recipient on those e-mails. 18 Correct? 19 A. Please find the attached signed 20 contract for your Gynemesh procedure 21 videos. The original and copies have been 22 sent to Jeff Kraut by the courier. 23 I see that. 24 Q. And if you look the "to" line,</p> | <p style="text-align: right;">Page 316</p> <p>1 you know, maneuvers you've done or -- or 2 anatomy you've shown might be used for 3 videos, and this might be like a little 4 segment video permission. 5 But I do not recall a video with 6 my name on it that I made for -- you know, 7 beginning to end for Ethicon. 8 Q. Well, if you look a little 9 further up in the chain on the same page, 10 there's an e-mail to you that says: 11 Larry. 12 That's you, right? 13 A. Yeah. 14 Q. (Reading) Would like to process 15 this payment in June. Need paperwork back 16 before 6/21. 17 Did I read that correctly? 18 A. Yep. 19 Q. So, were you paid to do this 20 video? 21 A. I don't know what I was doing 22 there. There's some -- I don't know -- I 23 don't know what this -- I don't know what 24 this is.</p> |
| <p style="text-align: right;">Page 315</p> <p>1 this e-mail was sent to you. 2 Correct? 3 A. Which line? 4 Yes. 5 Q. And who is Giselle Bonet? 6 A. I don't recall. 7 Q. And the subject line of this 8 exchange is called "Procedure Videos 9 Signed Contract." 10 Did I read that correctly? 11 A. Yep. 12 Q. I mean, did you do some form of 13 a video for Ethicon? 14 A. I don't think I did a 15 beginning-to-end video. I think perhaps 16 maybe in a lab they were filming some 17 steps of anatomic passage of something. 18 I -- I don't -- I cannot recall 19 a video that's got my name on it or in the 20 credits that the video maker of one of 21 these sling videos. 22 I think that sometimes when you 23 go to their labs and you work on stuff, 24 they ask you to sign permissions, or if,</p> | <p style="text-align: right;">Page 317</p> <p>1 Q. Okay. 2 A. I really don't know what it is. 3 Q. If you look on the next page, 4 there's an e-mail -- I mean on the front 5 page, I guess. There's an e-mail to you 6 on June 11th from Marianne Kaminski with 7 Ethicon stating: We have the signed 8 contract. We will process the payments. 9 Did I read that correctly? 10 A. Okay. 11 Q. So, appears you were paid for 12 doing a Gynecare -- excuse me. A Gynemesh 13 procedure video. 14 Right? 15 A. There's something I was doing 16 that was either used as part of a video or 17 participated in making a video. But as I 18 said, I don't recall. 19 As I've described it, it could 20 just be segments of something I did in a 21 lab that was filmed. 22 I don't believe that I made them 23 a video from beginning to end. But I was 24 clearly, by this set of e-mails, paid for</p> |

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| <p>1 work I did that was used as or as part of 2 creating a video. 3 Q. I really ask because I'm 4 wondering if I'm in the presence of a 5 movie star. That's really where I was 6 going with that. And if I could get an 7 autograph maybe later. 8 A. Well. 9 Q. All right. 10 A. But I do look like a couple of 11 them. 12 MR. DeGREEFF: Sir, I'll 13 happened you what I've marked as 14 Deposition Exhibit 14. 15 (Lind Exhibit 14, Q CDA Log, 16 Bates No. ETH.MESH.15359953 to 17 15359976, was marked for 18 identification, as of this date.) 19 BY MR. DeGREEFF: 20 Q. This is titled "Q CDA log." 21 Have you ever seen this before? 22 A. May have. 23 Q. If you look on page 11, the 24 Bates number at the bottom of it has a</p> | <p>1 A. Nope. 2 Q. Does it mean secrecy agreement? 3 MS. GERSTEL: Objection. 4 A. I don't know. 5 Q. Then there's a column further 6 over that has a term that says "term" and 7 it says "3." 8 Do you see that? 9 A. Yep. 10 Q. And it shows date and years 11 columns that says 12/19/2009 to 12 12/20/2012. 13 Do you see that? 14 A. Yep. 15 Q. So, were you under some form of 16 an agreement with them from 12/19 of 2009 17 to 12/20 of 2012? 18 A. Looks like they have a contract. 19 I don't know if this CDA log is accurate. 20 I'd like to see that contract. 21 I can certainly tell you between 22 those years, I do not have a lot of 23 activity with them. That's for sure. 24 Q. If you look at the originator</p> |
| Page 319 | Page 321 |
| <p>1 last three of '963. 2 A. Are they numbered? 3 Q. Down here (indicating). The 4 Bates number ends in '963. That's called 5 a Bates number. 6 A. Okay. 7 Q. If you look at the second column 8 over, it says: With whom. 9 A. Got it. 10 Q. And then one, two, three, fourth 11 one down says: Dr. Larry Lind. 12 I'm assuming that's you? 13 A. Yes. 14 Q. And that shows that there's a 15 topic next to it that says: Evaluating 16 information for discussions regarding 17 device evaluations. 18 Do you know what that means? 19 A. Sounds like I'm looking at their 20 devices and discussing it. 21 Q. If you look at the column next 22 to that, it says "type" and "SA" is 23 written. 24 Do you know what that means?</p> | <p>1 column, who is V. Zaddem? 2 A. I don't know what her position 3 is now. 4 I recall her name. 5 Q. Is it an Ethicon employee? 6 A. I assume it was someone 7 organizing or handling the contract, but I 8 don't know who it is. 9 Q. Do you know who Pete DeCosta is? 10 A. I do not. 11 Q. During this three years -- 12 MR. DeGREEFF: Strike that. 13 Q. Do you have any idea how much 14 you were being paid under this three years 15 of contracts? 16 A. I think there were very few 17 events. I was usually paid in the same 18 amount by them. 19 Q. The person below you on this 20 list is Dr. Elizabeth Kavalier. 21 Do you know her? 22 A. Yes. 23 Q. How do you know her? 24 A. She was a urologist in</p> |

| Page 322 | Page 324 |
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| <p>1 Manhattan. So we -- I get some of her 2 patients, she gets some of mine, and when 3 we do this Pelvic Floor Society meeting in 4 the city, she sometimes attends. I think 5 she was -- I think she was at the Prosima 6 lab that I did with them in this time 7 period, and I think that was probably the 8 only thing that I did with them in this 9 time period. I'm guessing, but I remember 10 I wasn't doing a lot. And they really 11 wanted me to look at this Prosima. 12 Q. Are you aware that she's also a 13 witness for Ethicon in the transvaginal 14 mesh litigations? 15 A. Yes. 16 Q. And you're aware that she was 17 also a consultant for Ethicon prior to 18 becoming an expert witness? 19 A. Yes. 20 Q. Are you aware of any expert 21 witness for Ethicon in this litigation 22 that was not a paid consultant first? 23 MS. GERSTEL: Objection. 24 A. I don't have an answer to that.</p> | <p>1 Q. So, this was a second agreement 2 with Ethicon that was covering the years 3 2010 to 2011. 4 Right? 5 We just looked at another one. 6 A. Those are the dates. 7 Q. So, during that time period, you 8 had multiple agreements with Ethicon? 9 A. It looks like I had these two. 10 MR. DeGREEFF: Sir, I'm handing 11 you what I've marked as Deposition 12 Exhibit 15. 13 (Lind Exhibit 15, e-mail chain 14 ending October 1, 2010, Bates No. 15 ETH.MESH.03642725 to 03642726, was 16 marked for identification, as of this 17 date.) 18 BY MR. DeGREEFF: 19 Q. Sir, I acknowledge that you are 20 not on this document. And really what I 21 want to ask you is there's a discussion 22 here about you, about your contract, in 23 which some employees of Ethicon state 24 they're going to look to terminate the</p> |
| Page 323 | Page 325 |
| <p>1 Q. Then if you look a couple pages 2 later where it says '965 as the last three 3 of the Bates number. 4 A. Okay. 5 Q. There's another in the column 6 that says with whom, if you go four down, 7 it says "Lawrence Lind." 8 I'm assuming that's also you? 9 A. I see it. 10 Q. And the column that says "topic" 11 says: Provide consulting services to 12 Ethicon on behalf of Ethicon. 13 Did I read that correctly? 14 A. I see it. 15 Q. It looks like you were under a 16 master consulting agreement from 8/31 of 17 2010 to 12/31 of 2011. 18 A. I see it. 19 Q. Does it sound accurate? 20 A. Yes. 21 Q. What did you do for Ethicon as 22 part of the consulting services from 2010 23 to 2011? 24 A. I don't recall.</p> | <p>1 marketing contract with you. 2 Do you see where I'm at on that? 3 A. Looking to terminate it. 4 Q. Yes. 5 A. Okay. 6 Q. Do you see where I'm at? 7 A. Yep. 8 Q. And it looks like the reason, 9 based on the e-mail above that, the reason 10 that they wanted to terminate the 11 marketing contract is because you had 12 signed an R&D agreement under which you 13 were going to get a different rate. 14 Right? 15 A. I wasn't aware as of this date 16 that I had a marketing agreement. My 17 understanding was always as consulting 18 services for education and research and 19 development. So I would need to see the 20 marketing agreement. I haven't seen 21 anything that we've looked at today that 22 says marketing. 23 I do see here that they seem to 24 feel that I had one and that they want to</p> |

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| <p style="text-align: right;">Page 326</p> <p>1 change it.</p> <p>2 Q. Why do you think they considered</p> <p>3 you to have a marketing contract?</p> <p>4 What kind of marketing were you</p> <p>5 doing for them?</p> <p>6 MS. GERSTEL: Objection.</p> <p>7 A. I wasn't.</p> <p>8 Q. Were you giving lectures for</p> <p>9 them?</p> <p>10 A. In labs I would teach the</p> <p>11 surgery and give educational lectures. I</p> <p>12 consider that education. If you consider</p> <p>13 it marketing at the same time, that's a --</p> <p>14 I don't know if that's a legal term or a</p> <p>15 judgment call of what you're doing, but I</p> <p>16 was educating.</p> <p>17 Q. In 2010, you were, based on this</p> <p>18 e-mail, you were also consulting for</p> <p>19 Boston Scientific.</p> <p>20 Right?</p> <p>21 A. Yes.</p> <p>22 Q. And you were wanting to craft</p> <p>23 the language of your consulting --</p> <p>24 MR. DeGREEFF: Strike that.</p> | <p style="text-align: right;">Page 328</p> <p>1 A. That's what the e-mail says.</p> <p>2 I haven't seen any contracts.</p> <p>3 MR. DeGREEFF: Sir, I'm going to</p> <p>4 hand you what I've marked as</p> <p>5 Deposition Exhibit 16.</p> <p>6 (Lind Exhibit 16, e-mail chain</p> <p>7 ending April 28, 2010, Bates No.</p> <p>8 ETH.MESH.02033638 to 02033639, was</p> <p>9 marked for identification, as of this</p> <p>10 date.)</p> <p>11 BY MR. DeGREEFF:</p> <p>12 Q. This again, this is an e-mail</p> <p>13 about an edit you were requesting to a</p> <p>14 contract in April of 2010.</p> <p>15 Right?</p> <p>16 A. Yep.</p> <p>17 Q. If you look at this first</p> <p>18 e-mail, the longer one, it says: I found</p> <p>19 Dr. Lind has existing contacts with ProfEd</p> <p>20 and marketing activities for product</p> <p>21 evaluation, written materials, market</p> <p>22 reviews, advisory boards and company</p> <p>23 sponsored speaker programs at a rate of</p> <p>24 \$1500 a day.</p> |
| <p style="text-align: right;">Page 327</p> <p>1 Q. You were wanting to craft the</p> <p>2 language of your R&D agreement with</p> <p>3 Ethicon to avoid any conflict to what you</p> <p>4 were doing for Boston Scientific.</p> <p>5 Is that something you remember?</p> <p>6 MS. GERSTEL: Objection.</p> <p>7 A. Yes. The contract said I</p> <p>8 couldn't work with anyone else on slings</p> <p>9 or incontinence materials, but I was</p> <p>10 already doing that with Boston Scientific.</p> <p>11 So I asked them to restrict the scope to</p> <p>12 repair a prolapse.</p> <p>13 Q. And if you look on the earliest</p> <p>14 e-mail on this exhibit, it says: There's</p> <p>15 a master consulting agreement for Dr.</p> <p>16 Lind.</p> <p>17 And it says: The contract term</p> <p>18 is one year beginning 2/25/10 and ending</p> <p>19 2/25/11.</p> <p>20 Did I read that correctly?</p> <p>21 A. Yep.</p> <p>22 Q. So that would be a third</p> <p>23 contract during that same time period.</p> <p>24 Right?</p> | <p style="text-align: right;">Page 329</p> <p>1 Did I read that correctly?</p> <p>2 A. Mm-hm.</p> <p>3 Q. Company sponsored speaking</p> <p>4 programs, were you speaking on behalf of</p> <p>5 the company, of Ethicon?</p> <p>6 A. Only at labs.</p> <p>7 Q. At labs?</p> <p>8 A. Yes.</p> <p>9 Q. And again, they're considering</p> <p>10 you to have a contract for marketing</p> <p>11 activities.</p> <p>12 Right?</p> <p>13 A. It does indicate that. I do not</p> <p>14 recall ever working on marketing.</p> <p>15 Q. Certainly it appears that</p> <p>16 Ethicon believed that they had a marketing</p> <p>17 contract with you.</p> <p>18 Right?</p> <p>19 MS. GERSTEL: Objection.</p> <p>20 A. I think what happened is we got</p> <p>21 involved in a time frame where companies</p> <p>22 and hospitals and doctors started</p> <p>23 recognizing compliance, and so that</p> <p>24 wording had to be very specific. So, they</p> |

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| <p style="text-align: right;">Page 330</p> <p>1 might have had stuff in the previous 2 agreements that had to do with marketing, 3 et cetera, et cetera, which is consulting 4 that I do not do. I only do work with the 5 R&D people. In fact, I don't interact 6 with the marketing people. It's part of 7 the rules. 8 So this is, I think, something 9 to get the accounting and compliance in 10 order that my role is for R&D, which is 11 what it always was. 12 Q. Whatever the case may be, we 13 looked at multiple e-mails now where 14 Ethicon refers to one of their contracts 15 with you as a marketing contract. 16 Right? 17 MS. GERSTEL: Objection. 18 A. I think those referrals to my 19 contracts and my role in there are wrongly 20 described. 21 Q. Regardless, that is the 22 terminology Ethicon is using, right? 23 A. And I am challenging it. 24 Q. Then if you look at down below</p> | <p style="text-align: right;">Page 332</p> <p>1 Did I read that correctly? 2 A. Everything you're reading you're 3 reading correctly. 4 Q. So, were you being paid \$1500 a 5 day for advisory board work? 6 A. That's what it says. 7 Q. And what does that advisory 8 board work mean? 9 A. You come and look at products. 10 You may be in a lab working on 11 development, discussing the products in 12 the setting of a cadaver lab. You may be 13 sitting around a table with other experts 14 holding mesh, feeling mesh, holding 15 devices, giving feedback as to what works, 16 what doesn't work, which directions can 17 they go. 18 Q. And then the last sentence on 19 this page leading to the next page says: 20 Over the past weekend, doctor made a 21 comment to one of our associates that he 22 was angered that he had signed at such a 23 low rate. Especially since he is 24 compensated by our competitors at \$3,000 a</p> |
| <p style="text-align: right;">Page 331</p> <p>1 there's an asterisk that says: These 2 activities are unique to Dr. Lind because 3 he uses competitor devices regularly. 4 Did I read that correctly? 5 A. Yes. 6 Q. And as we discussed earlier, you 7 use primarily the Caldera device 8 currently. 9 Right? 10 A. Currently. 11 At the time of this contract, I 12 think they were more interested in the 13 cadaver lab projects I did with Boston 14 Scientific. 15 Q. Gotcha. 16 So, this says: Here is what I 17 recently learned from Scott Jones in 18 marketing. 19 Do you know Scott Jones? 20 A. No. 21 Q. It says: In 2009, the doctor 22 agreed to \$1500 a day for Ad Board work, 23 which was the rate all participants 24 received for that event.</p> | <p style="text-align: right;">Page 333</p> <p>1 day for working with R&D. 2 Did I read that correctly? 3 A. Yes. 4 Q. So, you were upset that you were 5 only getting paid \$1500 a day by Ethicon 6 when your competitors were paying you 7 \$3,000 a day. 8 Right? 9 MS. GERSTEL: Objection. 10 A. I see the facts that are on this 11 sheet. 12 Q. Is that your recollection? 13 A. I don't have independent 14 recollection. 15 Q. Do you have any reason to 16 dispute this? 17 A. Not really. 18 Q. And what competitors were paying 19 you \$3,000 a day in 2009 and 2010? 20 A. Probably Boston Scientific. 21 Q. It also says: Also, this 22 surgeon has tried our pelvic floor 23 products many times, but he prefers to use 24 our competitors' products.</p> |

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1 Did I read that correctly?

2 A. Yes.

3 Q. And then they go on to say:

4 What I found out is that ProfEd - I guess

5 professional education - and marketing

6 used to use Dr. Lind heavily as a KOL

7 similar to how Dr. Vincent Lucente is

8 consulted currently. However, they do not

9 anticipate his services as specified in

10 his existing contracts because he does not

11 use Ethicon's PFR kits.

12 Did I read that correctly?

13 A. Yep.

14 Q. Do you know what a KOL is?

15 A. Key opinion leader.

16 Q. Were you a key opinion leader

17 for Ethicon?

18 A. I was a consultant. If they

19 called me that, they chose to call me

20 that.

21 It wasn't a badge you earned.

22 Q. Do you disagree that you were a

23 key opinion leader for Ethicon?

24 A. I think at times they thought I

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1 was and at times they thought I wasn't.

2 When I came to them with the slim sling

3 design, they told me to get lost, so.

4 Q. Okay.

5 A. My opinions weren't very

6 well-respected or received then.

7 Q. So you were a key opinion leader

8 for Ethicon when you were agreeing with

9 them.

10 Is that what you're saying?

11 MS. GERSTEL: Objection.

12 A. I don't have an answer for that.

13 Q. And it seems here that

14 professional education and marketing were

15 using you heavily.

16 Correct?

17 A. That's what it reads.

18 Q. Who is Dr. Vincent Lucente?

19 A. He's a urogynecologist in

20 Pennsylvania.

21 Q. Was he a key opinion leader for

22 Ethicon?

23 MS. GERSTEL: Objection.

24 A. I guess he was.

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1 THE WITNESS: I'm sorry. I know

2 time is getting tight. I'm going to

3 use the restroom.

4 MS. GERSTEL: Okay.

5 (Recess taken.)

6 (Lind Exhibit 17, e-mail chain

7 ending May 10, 2010, Bates No.

8 HMESH_ETH_03111719, was marked for

9 identification, as of this date.)

10 BY MR. DeGREEFF:

11 Q. Sir, I've just handed you what

12 I've marked Deposition Exhibit 17.

13 Do you see that?

14 A. Yep.

15 Q. This is some e-mail exchanges

16 from April of 2010.

17 Correct?

18 A. These are e-mails from 2010,

19 yes.

20 Q. And the first e-mail on the

21 chain is an e-mail that you sent to

22 Vincenza Zaddem.

23 Right?

24 A. I reviewed the contract.

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1 Q. If you just look at the to/from

2 line and the e-mail.

3 A. Yeah. I see the one with me to

4 Zaddem, yes.

5 Q. And who is Zaddem?

6 A. I don't know.

7 Q. Really my only question is if

8 you look at that, you say: I reviewed the

9 contract.

10 Correct?

11 A. Yes.

12 Q. And then under item 17, the

13 paragraph that starts with the words "item

14 17," the last sentence is: The value of

15 the contract does not justify exclusive

16 services.

17 Did I read that correctly?

18 A. Yes.

19 Q. What was the value of this

20 contract?

21 MS. GERSTEL: Objection.

22 A. The value of the contract had

23 standard terms of just hourly rate for --

24 for work done. It entire set -- this

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| <p style="text-align: right;">Page 338</p> <p>1 entire conversation is about what we were 2 eluding to before insofar as I do 3 consulting with other companies on 4 incontinence and prolapse. The way that 5 they had the contract written, I wouldn't 6 be able to work with anyone else on 7 incontinence and prolapse. So what I was 8 telling them was that you need to, as you 9 have in the previous one where it says the 10 contract must be limited to anchoring 11 devices for prolapse, something specific 12 that we're working on that makes it 13 specific to what I'm doing for Ethicon, 14 because I couldn't sign the contract 15 because it made it so I couldn't work with 16 anyone else. It wasn't like I was being 17 offered \$40,000 or some big sum to have an 18 exclusivity arrangement. 19 What I meant by exclusive 20 services meaning exclusive of other 21 companies. That's just a standard 22 contract. Didn't work. 23 So, you know, I remember this 24 freshly now.</p> | <p style="text-align: right;">Page 340</p> <p>1 A. Yes. With the only 2 clarification to make when we went to 3 the -- when we were doing the study, the 4 study payments are a hundred percent paid 5 to the hospital research fund, and there's 6 no compensation part out of that for me. 7 Q. Okay. 8 And what amount would have 9 justified exclusivity? 10 A. I actually -- it's -- I wouldn't 11 do that. I think with -- you've just gone 12 through a whole bunch of papers showing 13 that I've worked with a lot of different 14 companies on consulting arrangements, and 15 what I'll tell you is that when I have an 16 idea and I find the person I can work with 17 on it, I go there. So it's not a matter 18 of trying to just make money off of 19 everyone. There's different opportunities 20 at different times with different 21 companies are ready for different ideas. 22 So -- so, I never considered an 23 exclusive agreement with anyone, which is 24 why I contested the wording in the</p> |
| <p style="text-align: right;">Page 339</p> <p>1 We went back and forth, back and 2 forth. And they said, Everyone just signs 3 these. I said, Well, maybe everyone 4 doesn't read it. If your contract says I 5 can't work with anyone else, then I won't 6 work with anyone else. So if you want me 7 to look at these anchoring devices, which 8 is what they wanted me to do, then make 9 the language for the anchoring device, but 10 don't make it to cover that you can't work 11 on anyone else for anything else that you 12 do. 13 So really it was just the 14 wording of their contract meant that I 15 could work with anyone on incontinence and 16 prolapse, and I was asking them to make a 17 contract that was just specific to what 18 they wanted me to look at, which was an 19 anchoring device. 20 Q. And these amounts you're being 21 paid for consulting work, that's above and 22 beyond what you're being paid as a 23 physician. 24 True?</p> | <p style="text-align: right;">Page 341</p> <p>1 contract. 2 Q. Everything we've gone through, I 3 mean, you've been paid over half a million 4 dollars as on behalf of the transvaginal 5 mesh world, if you will. 6 Right? 7 MS. GERSTEL: Objection. 8 BY MR. DeGREEFF: 9 Q. The manufacturers? 10 MS. GERSTEL: Objection. 11 MR. DeGREEFF: Strike that. 12 I'll reword that. 13 Q. Based on everything we've been 14 through, you've been paid over a half 15 million dollars by transvaginal mesh 16 manufacturers. 17 True? 18 MS. GERSTEL: Objection. 19 A. I don't know if that's accurate. 20 It's definitely in the hundreds of 21 thousands. I don't know how many it is. 22 I would have to be -- I don't know how 23 many occasions I saw each of these 24 Gynecare contracts. I don't have the</p> |

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| <p style="text-align: right;">Page 342</p> <p>1 listed payments for. There's a lot of 2 years of contracts, and I'm not sure how 3 frequent those were. 4 Q. Well, when you add in what 5 you've been paid as an expert witness, 6 it's pretty clear you've been paid over a 7 half million dollars by the transvaginal 8 mesh industry. 9 Right? 10 MS. GERSTEL: Objection. 11 A. You may have been adding those. 12 Somewhere between 300 and 600 I would 13 agree with somewhere in there. I just 14 don't want to agree to a number that I 15 haven't quantified with a little more 16 conviction. 17 MR. DeGREEFF: I've handed you 18 what's been marked as Deposition 19 Exhibit 18. 20 (Lind Exhibit 18, Master 21 Consulting Agreement between Lawrence 22 Lind and Ethicon, Inc. Dated July 10, 23 2010, Bates No. ETH.MESH.06216861 to 24 06216869, was marked for</p> | <p style="text-align: right;">Page 344</p> <p>1 maximum over the life of this contract? 2 A. That's what it says. 3 Q. And that's the estimate, 4 obviously. 5 A. Yes. 6 Q. And then it says: The parties 7 agree that compensation paid to consultant 8 shall not exceed \$52,500 per contract 9 term. 10 A. Right. 11 Q. Did I read that correctly? 12 A. Yes. 13 Q. And the contract term was a 14 little over a year. 15 Is that right? 16 A. Yes. 17 Q. Were you paid this full \$52,500? 18 A. I would strongly doubt that in 19 2010. 20 Q. If you could look at the next 21 page. I guess they were authorizing you 22 to be paid 52,500 for the year under this 23 contract. 24 Right?</p> |
| <p style="text-align: right;">Page 343</p> <p>1 identification, as of this date.) 2 BY MR. DeGREEFF: 3 Q. Sir, do you see that this is a 4 master consulting agreement between you 5 and Ethicon? 6 A. Right. 7 Q. And it's dated July 10th -- 8 well, it says it commences July 10th of 9 2010 and continues through December 31st 10 of 2011? 11 A. Right. 12 Q. My question is if you look at 13 where it's Bates numbered '868 at the 14 bottom. 15 A. Okay. 16 Q. This talks about the fact that 17 you're being retained, the box where it 18 says yes, you're being retained at a rate 19 of \$437.50 per hour. 20 Correct? 21 A. That's what it says. 22 Q. And it lays out the description 23 of your services and the fact that it will 24 be an estimate of 120 hours of work</p> | <p style="text-align: right;">Page 345</p> <p>1 A. They were offering that to be a 2 max based on the hourly fee. 3 Q. If you look at Exhibit B, this 4 is titled "Conflict of Interest 5 Certification"? 6 A. Yeah. 7 Q. And it states, and this is 8 supposed to be from you. 9 Correct? 10 MR. DeGREEFF: Let's do this. 11 This one is unsigned. So let's give 12 you this one. 13 Sir, I'm going to hand you 14 what's been marked as Deposition 15 Exhibit 19. 16 (Lind Exhibit 19, Master 17 Consulting Agreement between Lawrence 18 Lind and Ethicon, Inc. Dated August 19 31, 2010, Bates No. ETH.MESH.02030557 20 to 02030566, was marked for 21 identification, as of this date.) 22 BY MR. DeGREEFF: 23 Q. Deposition Exhibit 19 is another 24 master consulting agreement between you</p> |

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| <p style="text-align: right;">Page 346</p> <p>1 and Ethicon. 2 Correct? 3 A. Right. 4 Q. And it's dated -- it says it 5 commences August 31st of 2010 and 6 continues through December 31st of 2011. 7 Right? 8 A. Yeah. This is kind of confusing 9 that they have like fresh contracts every 10 month. 11 But be that as it may. 12 Q. Right. 13 And this contract is signed by 14 you. 15 Correct? Bates number '562. 16 A. Yes. 17 Q. Then if you look at Bates number 18 '564, this has the same language about 19 payment to you. 20 Correct? 21 MS. GERSTEL: Objection. 22 A. Right. 23 Q. Again you're being paid \$437.50 24 an hour?</p> | <p style="text-align: right;">Page 348</p> <p>1 and industry may create conflicts of 2 interest, both real and perceived. 3 Did I read that correctly? 4 A. Yes. 5 Q. This is essentially Ethicon 6 acknowledging that payments to physicians, 7 such as -- 8 MR. DeGREEFF: Strike that. 9 Q. This is Ethicon acknowledging 10 that payments to physicians can create 11 conflicts of interest. 12 Right? 13 MS. GERSTEL: Objection. 14 A. Got it. 15 Q. Is that correct? 16 MS. GERSTEL: Objection. 17 A. Which sentence are you reading 18 again? 19 Q. Where it states: The 20 undersigned health care professional 21 agrees that financial ties between the 22 health care professional and industry may 23 create conflicts of interest, both real 24 and perceived.</p> |
| <p style="text-align: right;">Page 347</p> <p>1 A. Yep. 2 Q. And you've got another maximum 3 cap of \$52,500 per contract term? 4 A. Correct. 5 Q. Again, that contract term is a 6 little over a year? 7 A. Okay. 8 Q. Is that correct? 9 A. Yes. 10 Q. Then if you look at the next 11 page, it's got an Exhibit B titled 12 "Conflict of Interest Certification." 13 Correct? 14 A. Right. 15 Q. And that is signed by you? 16 A. Yes. 17 Q. And that includes language that 18 states: In assuming contractual 19 obligations to Ethicon Inc., the 20 undersigned health care professional. 21 That's you, right? 22 A. Yes. 23 Q. (Reading) Agrees that financial 24 ties between the health care professional</p> | <p style="text-align: right;">Page 349</p> <p>1 A. Okay. I agree. I agree that's 2 what it says. 3 Q. And is this essentially Ethicon 4 acknowledging that payments to physicians 5 can create conflicts of interest? 6 MS. GERSTEL: Objection. 7 A. That they may create conflicts 8 of interest, yes. 9 Q. We just talked about you've been 10 paid between 300 and 600,000 by the 11 transvaginal mesh industry. 12 Right? 13 MS. GERSTEL: Objection. 14 A. By estimates, it seems it would 15 be in that range. 16 Q. And you've been a consultant for 17 four transvaginal mesh companies. 18 Right? 19 A. Yes. 20 Q. You've been a consultant for 21 Ethicon. 22 Right? True? 23 A. Yes. 24 Q. Caldera?</p> |

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1 A. Yes.
2 Q. Boston Scientific?
3 A. Yes.
4 Q. AMS?
5 A. Yes.
6 Q. And you've been referred to as a
7 key opinion leader for Ethicon products by
8 internal Ethicon employees.
9 Right?
10 A. Yes.
11 Q. And you've been referred to as
12 having a marketing contract with Ethicon
13 by Ethicon employees.
14 Right?
15 A. Referred to, yes.
16 Q. And we've looked at multiple
17 consulting agreements that you've signed
18 with Ethicon.
19 True?
20 A. Yes.
21 Q. And you've signed a conflict of
22 interest statement from Ethicon based on
23 the fact that payments to health care
24 providers can create conflicts of

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1 interest, both real and perceived.
2 Right?
3 A. Correct.
4 Q. Despite all of that, you were
5 ultimately hired by Ethicon to act as a
6 expert in this litigation.
7 Right?
8 MS. GERSTEL: Objection.
9 A. I'm not sure why it's despite
10 this. But I was hired by Ethicon to be in
11 this role that I am now.
12 I'm not sure how your one thing
13 with the word "despite," I'm not sure how
14 that fits into the question.
15 Q. You've now been hired by Ethicon
16 to serve as an expert in this transvaginal
17 mesh litigation.
18 Right?
19 A. Yes.
20 Q. And do you have any understanding
21 of why Ethicon did not get a physician who
22 did not have a consulting agreement with
23 prior to hiring them as an expert witness
24 in the litigation?

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1 MS. GERSTEL: Objection; lack of
2 foundation.
3 A. I would be conjecturing. I
4 don't have factual knowledge.
5 Is there a question on this?
6 Q. We had several questions on it.
7 A. Okay.
8 MR. DeGREEFF: Last I want to
9 show you Deposition Exhibit 20. I so
10 marked that.
11 (Lind Exhibit 20, EWHU HCP
12 Cognos report run 11/17/10, was marked
13 for identification, as of this date.)
14 BY MR. DeGREEFF:
15 Q. If you look at the second page,
16 you'll find your name towards the bottom.
17 A. Okay.
18 Q. This shows two separate -- this
19 reflects the two separate contracts of
20 52,500.
21 Correct?
22 A. Right.
23 Q. For a total of 105,000?
24 A. Right.

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1 Q. So you had been authorized by
2 Ethicon for up to \$105,000 of payment for
3 a little over a year.
4 Right?
5 MS. GERSTEL: Objection.
6 A. I think this is misleading. The
7 maximal allowed in the contract was that
8 amount, and this reflects nothing in the
9 way of what I actually received.
10 Q. That wasn't my question.
11 You were authorized by Ethicon
12 for up to \$105,000 worth of payment in one
13 year.
14 Right?
15 MS. GERSTEL: Objection.
16 A. If I worked \$437 an hour to get
17 to \$105,000.
18 Q. Okay.
19 Or if they wanted pay you \$3,000
20 to show up to a lecture.
21 Right?
22 MS. GERSTEL: Objection.
23 A. The contract had an hourly rate.
24 Q. Okay.

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| <p style="text-align: right;">Page 354</p> <p>1 Why was there two different</p> <p>2 agreements? Did you use all of one of</p> <p>3 them?</p> <p>4 MS. GERSTEL: Objection.</p> <p>5 A. It looks to me like on the first</p> <p>6 one I hadn't signed the institutional</p> <p>7 compliance that I -- that my working for</p> <p>8 them did not violate institutional</p> <p>9 compliance for doing consulting work.</p> <p>10 So one of them had a signature</p> <p>11 and one of them did not. So I think they</p> <p>12 sent a whole new contract to have me sign</p> <p>13 that last page, is what I -- it looks like</p> <p>14 to me from the two.</p> <p>15 Q. Why does this spreadsheet</p> <p>16 reflect that you had two separate --</p> <p>17 MS. GERSTEL: Objection.</p> <p>18 A. Well, we looked at two separate</p> <p>19 ones, and you'll see one of them the last</p> <p>20 page is not signed and one of them the</p> <p>21 page is signed. So they made two</p> <p>22 contracts for that amount. I'm guessing</p> <p>23 that the first one they considered to be</p> <p>24 legally not binding because I didn't sign</p> | <p style="text-align: right;">Page 356</p> <p>1 randomized controlled trial specifically</p> <p>2 addressing the TVT-O?</p> <p>3 A. TVT-O has in the range of 40 to</p> <p>4 50 randomized trials. I'd have to go</p> <p>5 through them to figure out how far the</p> <p>6 long-term is.</p> <p>7 Q. What about a single randomized</p> <p>8 control trial specifically addressing the</p> <p>9 TVT-O with safety as the primary endpoint?</p> <p>10 MS. GERSTEL: Objection.</p> <p>11 A. Safety is a primary endpoint in</p> <p>12 many of the randomized controlled studies.</p> <p>13 Whether they listed efficacy first and</p> <p>14 safety as second, I would have to go</p> <p>15 through each report, but safety was</p> <p>16 reported in a very large number of them.</p> <p>17 I will agree that in some of</p> <p>18 them the adverse events data was not</p> <p>19 accurately reported, which is why we rely</p> <p>20 on Cochrane and excellent meta-analysis so</p> <p>21 that they include studies that have the</p> <p>22 data we need.</p> <p>23 Q. What is your definition of</p> <p>24 primary endpoint? Because I think it may</p> |
| <p style="text-align: right;">Page 355</p> <p>1 that required field, and they made another</p> <p>2 one and it's showing up on here because</p> <p>3 two contracts were drawn.</p> <p>4 But it's -- it's line items on a</p> <p>5 spreadsheet. I can't account for them. I</p> <p>6 can -- I am 1,000 percent sure I didn't</p> <p>7 come anywhere close to this kind of money</p> <p>8 from 2010 on with Ethicon.</p> <p>9 Q. That assumption is based on --</p> <p>10 what you just said requires us to assume</p> <p>11 that we have received all of the documents</p> <p>12 that we would need to show the signing of</p> <p>13 that contract.</p> <p>14 Correct?</p> <p>15 MS. GERSTEL: Objection.</p> <p>16 A. Yeah, I agree. We don't right</p> <p>17 now between us have the accounting</p> <p>18 accurate payroll of what was paid. But</p> <p>19 just knowing what I was doing with time in</p> <p>20 2010 onward, I feel fairly confident, but</p> <p>21 I don't have your objective proof, that I</p> <p>22 came nowhere near that, but I am very</p> <p>23 confident of that.</p> <p>24 Q. Is there a single long-term</p> | <p style="text-align: right;">Page 357</p> <p>1 be different than mine.</p> <p>2 A. Primary endpoint is the first</p> <p>3 and -- first priority end point result</p> <p>4 you're looking for in a study.</p> <p>5 Q. Right.</p> <p>6 And you think there's a single</p> <p>7 long-term randomized study out there with</p> <p>8 safety as the primary endpoint on the</p> <p>9 TVT-O product?</p> <p>10 A. I don't think it's as a primary</p> <p>11 endpoint because it's pretty traditional</p> <p>12 to do efficacy and then safety. But a</p> <p>13 second endpoint doesn't diminish its</p> <p>14 value, statistical value.</p> <p>15 Q. So the answer to my question as</p> <p>16 asked is "no."</p> <p>17 Right?</p> <p>18 MS. GERSTEL: Objection.</p> <p>19 A. I would have to look through all</p> <p>20 the randomized studies to do that. I</p> <p>21 don't know that offhand.</p> <p>22 Certainly most of them don't</p> <p>23 have it as the primary.</p> <p>24 Q. What about is there a single</p> |

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| <p style="text-align: right;">Page 358</p> <p>1 randomized controlled trial with safety as 2 the primary endpoint that specifically 3 addresses the TVT-Abbrevio? 4 MS. GERSTEL: Objection. 5 A. I think your primary endpoint is 6 a -- from the challenging the data on this 7 as a primary endpoint is on the verge of 8 incredible. 9 MR. DeGREEFF: Okay. I 10 appreciate your thoughts on that. I 11 really do. And I'll move to strike 12 it. But I do want an answer to my 13 question. 14 A. I would have to review each of 15 them to see which ones have primary 16 endpoints. I don't know off the top of my 17 head if they have primary endpoints. So I 18 don't know the answer to that question. 19 Q. And then same question for 20 TVT-Exact. 21 Is there a single long-term 22 randomized controlled trial with safety as 23 the primary endpoint specifically 24 addressing the TVT-Exact?</p> | <p style="text-align: right;">Page 360</p> <p>1 head, I would have to find the document. 2 I think it was determined that they felt 3 it would not be a significant difference. 4 Q. Are you talking about testing or 5 a study? 6 MS. GERSTEL: Objection. 7 A. Mechanical testing. 8 Q. I'm talking about a study. 9 Ethicon's never done a study 10 where the primary endpoint is to determine 11 whether or not laser-cut mesh is stiffer 12 and less safe than mechanical-cut mesh. 13 Correct? 14 MS. GERSTEL: Objection. 15 A. A study in humans? 16 What type of study. 17 Q. Any kind of study. 18 A. Well, a lab is a study. 19 Q. Well, lab's a benchtop, right? 20 A. A study is when you investigate 21 to find answers. It doesn't matter what 22 location it's in, whether it's a lab or in 23 a human. It can be a study. 24 Q. I think you and I define a study</p> |
| <p style="text-align: right;">Page 359</p> <p>1 A. That one I think I could tell 2 you is no. 3 Q. Is there a single long-term 4 randomized controlled study with safety as 5 the primary endpoint that looks at the 6 TVT? 7 MS. GERSTEL: Objection. 8 A. I'd have to look at the -- each 9 randomized study. I can't answer that off 10 the top of my head. 11 Q. There's not one you could think 12 of? 13 A. Not off the top of my head. 14 Q. Ethicon has never done a study 15 with the primary endpoint was to determine 16 where or not laser-cut mesh is stiffer or 17 safer than mechanical-cut mesh. 18 Right? 19 MS. GERSTEL: Objection. 20 A. I seem to recall there being 21 some internal study of the laser-cut mesh. 22 I can't recall all the details on it, but 23 I think they did study the properties. If 24 I recall, and again it's off the top of my</p> | <p style="text-align: right;">Page 361</p> <p>1 different. 2 You're talking about benchtop 3 testing. 4 Right? 5 A. I'm talking about comparing 6 properties. You compare one thing against 7 another is the definition of a study. 8 Q. So anything that's ever done at 9 Ethicon is a study, even if they're just 10 doing it on a bench? 11 MS. GERSTEL: Objection. 12 A. Well, if we're just chatting 13 about the study, it's not a study. 14 If they have two products and 15 they're comparing how it behaves in 16 different circumstances, that's a study. 17 Q. So, I guess can you answer my 18 question or not? 19 And my question is Ethicon has 20 never done a study where the primary 21 endpoint is to determine whether or not 22 laser-cut mesh is stiffer and less safe 23 than mechanical-cut mesh? 24 MS. GERSTEL: Objection.</p> |

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| <p style="text-align: right;">Page 362</p> <p>1 BY MR. DeGREEFF:</p> <p>2 Q. True?</p> <p>3 MS. GERSTEL: Asked and</p> <p>4 answered.</p> <p>5 A. If I'm recalling correctly, and</p> <p>6 I cannot put my reputation on it, I think</p> <p>7 the bench work study that they did looked</p> <p>8 at stiffness, but they couldn't, by that</p> <p>9 study, evaluate safety.</p> <p>10 Q. We talked earlier about the</p> <p>11 Ethicon employees' e-mails about concerns</p> <p>12 about the outcomes related to stiffness of</p> <p>13 the mesh.</p> <p>14 Right?</p> <p>15 MS. GERSTEL: Objection.</p> <p>16 A. We had that discussion, I do</p> <p>17 recall.</p> <p>18 MR. DeGREEFF: I'm good. We can</p> <p>19 be done.</p> <p>20 MS. GERSTEL: I have like five</p> <p>21 minutes.</p> <p>22 Do you want to take a break, or</p> <p>23 should I just start?</p> <p>24 MR. DeGREEFF: Go for it.</p> | <p style="text-align: right;">Page 364</p> <p>1 A. Yes.</p> <p>2 Q. And, doctor, you were asked some</p> <p>3 questions regarding Abbrevio being a</p> <p>4 shorter sling than TVT-O and TVT-Exact.</p> <p>5 Do you recall that?</p> <p>6 A. Yes.</p> <p>7 Q. Is it correct that even though</p> <p>8 Abbrevio is not as long as a TVT-Exact or a</p> <p>9 TVT-O or a retropubic TVT that it is not a</p> <p>10 mini sling?</p> <p>11 MR. DeGREEFF: Object to form.</p> <p>12 A. I agree with that.</p> <p>13 MR. DeGREEFF: You want to just</p> <p>14 give me an ongoing objection to</p> <p>15 leading?</p> <p>16 MS. GERSTEL: Yes. Although I</p> <p>17 disagree that was leading.</p> <p>18 MR. DeGREEFF: Well, you can't</p> <p>19 testify for him.</p> <p>20 MS. GERSTEL: I'm not testifying</p> <p>21 for him.</p> <p>22 MR. DeGREEFF: That's what</p> <p>23 you're doing right now.</p> <p>24 MS. GERSTEL: I am not</p> |
| <p style="text-align: right;">Page 363</p> <p>1 MS. GERSTEL: I know we're all</p> <p>2 running on fumes.</p> <p>3 EXAMINATION BY</p> <p>4 MS. GERSTEL:</p> <p>5 Q. Dr. Lind, you were asked some</p> <p>6 questions about the Advantage Fit Boston</p> <p>7 Scientific sling that you had a role in</p> <p>8 developing.</p> <p>9 Is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. Is it your opinion, despite that</p> <p>12 role in developing the Advantage Fit</p> <p>13 sling, that retropubic TVT is the gold</p> <p>14 standard?</p> <p>15 MR. DeGREEFF: I'm going to</p> <p>16 object to form.</p> <p>17 BY MS. GERSTEL:</p> <p>18 Q. For surgical treatment of stress</p> <p>19 urinary incontinence in women?</p> <p>20 A. Yes.</p> <p>21 Q. Did the vast majority of your</p> <p>22 patients have excellent results with</p> <p>23 retropubic TVT?</p> <p>24 MR. DeGREEFF: Object to form.</p> | <p style="text-align: right;">Page 365</p> <p>1 testifying for him. I asked him --</p> <p>2 MR. DeGREEFF: I'll just keep</p> <p>3 objecting. That's fine.</p> <p>4 BY MS. GERSTEL:</p> <p>5 Q. Doctor, you were asked some</p> <p>6 questions regarding your own experience</p> <p>7 and results treating patients with TVT-O,</p> <p>8 TVT-Exact, and TVT-Abbrevio.</p> <p>9 Is that correct?</p> <p>10 A. Yes.</p> <p>11 Q. Is your own experience with</p> <p>12 TVT-O, TVT-Abbrevio, and TVT-Exact</p> <p>13 consistent with what you have opined on as</p> <p>14 to the safety and efficacy of those</p> <p>15 products as based on the highest levels of</p> <p>16 medical literature?</p> <p>17 MR. DeGREEFF: Object to form.</p> <p>18 A. Yes.</p> <p>19 Q. Doctor, you were asked some</p> <p>20 questions about what you have and have not</p> <p>21 reviewed --</p> <p>22 MS. GERSTEL: Strike that.</p> <p>23 Q. Doctor, you were asked some</p> <p>24 questions regarding your supplemental</p> |

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1 materials list.
 2 Correct?
 3 A. Yes.
 4 Q. And you were asked some
 5 questions regarding which of the documents
 6 on that list you had or had not reviewed.
 7 Correct?
 8 A. Yes.
 9 Q. Doctor, is it true that you read
 10 many, many medical articles and company
 11 documents and depositions and other such
 12 materials since you began your expert work
 13 with Ethicon?
 14 MR. DeGREEFF: Object to form.
 15 A. Yes.
 16 Q. As you sit here today, is it
 17 true that you may or may not recall
 18 specific documents that you have reviewed
 19 that are listed on your materials list?
 20 MR. DeGREEFF: Object to form.
 21 A. That's true.
 22 Q. And is that particularly true if
 23 you weren't shown the document when asked
 24 if you had or had not reviewed them?

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1 MR. DeGREEFF: Object to form.
 2 A. Yes.
 3 Q. I think that this was adequately
 4 covered by plaintiff's counsel's
 5 questioning.
 6 But, doctor, were you asked some
 7 questions regarding whether you had --
 8 MS. GERSTEL: Well, strike that.
 9 Q. Doctor, earlier in this
 10 deposition you testified regarding closer
 11 analysis that you have done recently of
 12 the Schimpf, Teo, and Okulu articles.
 13 Is that correct?
 14 A. Yes.
 15 Q. After that closer analysis of
 16 those articles, did your opinions as
 17 expressed in your report that's been
 18 marked as Exhibit 8, did your opinions
 19 change as a result of that closer analysis
 20 of those articles?
 21 A. It didn't. It became
 22 strengthened with regards to the safety
 23 profile of the TVT-O.
 24 MS. GERSTEL: That's all I have.

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1 MR. DeGREEFF: I just have two
 2 questions.
 3 FURTHER EXAMINATION BY
 4 MR. DeGREEFF:
 5 Q. Which device did you agree with
 6 counsel was the gold standard device?
 7 A. I would say the retropubic TVT
 8 as well as the TVT-O.
 9 Q. Okay.
 10 Why are you not using the gold
 11 standard device?
 12 MS. GERSTEL: Objection.
 13 A. I do use the TVT-Exact, which I
 14 consider to be the extremely similar
 15 device with a modification that I like,
 16 which is a narrower shaft.
 17 Q. You use it in one out of ten of
 18 your patients?
 19 A. Right.
 20 Q. Why would you not use the gold
 21 standard device in all of your patients?
 22 MS. GERSTEL: Objection.
 23 A. Because there was a -- there was
 24 a decision at one point to bring on

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1 Caldera for financial reasons. At that
 2 point, we were asked to convert over to
 3 that and see if it met our needs. It met
 4 my needs, and I like the flexibility, and
 5 I started using it for good fraction of my
 6 cases.
 7 Q. Are you breaching the standard
 8 of care by not using the gold standard
 9 device?
 10 MS. GERSTEL: Objection.
 11 A. I'm using an FDA-approved device
 12 that I feel is excellent for its intended
 13 purposes, and it's been performing well
 14 for several years.
 15 Q. Yes or no, you are not using
 16 what you just testified is the gold
 17 standard device.
 18 Correct?
 19 MS. GERSTEL: Objection.
 20 A. I'm using the TVT-Exact in
 21 one-tenth of my cases, yes.
 22 Q. In 90 percent of your cases, you
 23 are not using the device you have just
 24 testified is the gold standard device.

| Page 370 | Page 372 |
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| <p>1 Right?</p> <p>2 MS. GERSTEL: Objection.</p> <p>3 A. Correct.</p> <p>4 Q. You were asked by your counsel</p> <p>5 if --</p> <p>6 MR. DeGREEFF: Strike that. It</p> <p>7 doesn't matter.</p> <p>8 All right. I'm done.</p> <p>9 MS. GERSTEL: I just have one</p> <p>10 follow-up.</p> <p>11 FURTHER EXAMINATION BY</p> <p>12 MS. GERSTEL:</p> <p>13 Q. Doctor, this isn't a document</p> <p>14 that we have marked as an exhibit in this</p> <p>15 deposition, but are you familiar with the</p> <p>16 AUGS SUFU position statement on</p> <p>17 midurethral slings?</p> <p>18 THE WITNESS: Actually, I need</p> <p>19 it -- I think I answered incorrectly</p> <p>20 on your last question.</p> <p>21 MR. DeGREEFF: Well, we've got a</p> <p>22 different question pending now. So if</p> <p>23 your counsel wants to clear something</p> <p>24 up with you, she can ask you a</p> | <p>1 then they give their -- they give their</p> <p>2 affirmation and every authoritative agency</p> <p>3 that's approving and ratifying midurethral</p> <p>4 slings as the standard of care ratifies</p> <p>5 midurethral slings.</p> <p>6 So, it is -- while would</p> <p>7 certainly agree that the largest amount of</p> <p>8 data on midurethral slings comes from</p> <p>9 Ethicon, the number of time and decades</p> <p>10 and years and studies that have proven</p> <p>11 that the results are similar make it a</p> <p>12 midurethral sling and not necessarily a</p> <p>13 Gynecare TVT midurethral sling which is</p> <p>14 the standard of care.</p> <p>15 So, in that regard, I continue</p> <p>16 to use the standard of care.</p> <p>17 MR. DeGREEFF: Okay. I'm going</p> <p>18 to ask a follow-up question. I'll let</p> <p>19 your counsel finish.</p> <p>20 MS. GERSTEL: Okay.</p> <p>21 BY MS. GERSTEL:</p> <p>22 Q. Doctor, I think you anticipated</p> <p>23 what my question was going to be.</p> <p>24 First, doctor, I believe that</p> |
| Page 371 | Page 373 |
| <p>1 question.</p> <p>2 THE WITNESS: It has to do with</p> <p>3 the gold standard.</p> <p>4 MS. GERSTEL: Go ahead.</p> <p>5 MR. DeGREEFF: No, she can ask</p> <p>6 you a question if she wants to ask you</p> <p>7 something about it.</p> <p>8 BY MS. GERSTEL:</p> <p>9 Q. Doctor, what were you going to</p> <p>10 say?</p> <p>11 MR. DeGREEFF: I'm going to</p> <p>12 object to the form. That's open-ended</p> <p>13 and allows for a narrative response.</p> <p>14 A. Well, the TVT by Ethicon has the</p> <p>15 preponderance of the data. The</p> <p>16 meta-analyses that go over all the slings</p> <p>17 and all the data for slings certifies</p> <p>18 polyester synthetic midurethral slings as</p> <p>19 the gold standard of care. The</p> <p>20 meta-analysis do not specify Gynecare TVT</p> <p>21 as the standard of care.</p> <p>22 So, Ford and Cochrane specify</p> <p>23 that tapes that pass in the obturator</p> <p>24 pathway and in the retropubic pathway, and</p> | <p>1 you just misspoke now when you said</p> <p>2 "polyester."</p> <p>3 Did you mean polypropylene?</p> <p>4 A. Yes.</p> <p>5 Q. And, doctor, I'll just re-ask</p> <p>6 that question.</p> <p>7 Are you familiar with the AUGS</p> <p>8 SUFU position statement on mesh</p> <p>9 midurethral slings?</p> <p>10 A. Yes.</p> <p>11 Q. And does that position statement</p> <p>12 refer to polypropylene type 1 macroporous</p> <p>13 mesh midurethral slings regardless of</p> <p>14 route, transvaginally or retropubic, as</p> <p>15 the gold standard in surgical treatment</p> <p>16 for stress urinary incontinence in women?</p> <p>17 A. Yes, it does.</p> <p>18 Q. And do you agree with that</p> <p>19 opinion?</p> <p>20 A. I do.</p> <p>21 MS. GERSTEL: That's all I have.</p> <p>22</p> <p>23</p> <p>24</p> |

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1 FURTHER EXAMINATION BY
2 MR. DeGREEFF:
3 Q. Doctor, you are now withdrawing
4 your earlier statement that the TVT
5 products are the gold standard.
6 Correct?
7 MS. GERSTEL: Objection.
8 A. I would say based on the
9 meta-analysis, yes.
10 Q. What your testimony is is that
11 you believe midurethral slings to be the
12 gold standard.
13 Right?
14 A. Yes.
15 MR. DeGREEFF: No further
16 questions.
17 (Deposition adjourned at
18 approximately 7:57 p.m.)
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1 A C K N O W L E D G M E N T
2
3 STATE OF)
4 :ss
5 COUNTY OF)
6
7 I, LAWRENCE LIND, M.D., hereby
8 certify that I have read the transcript of
9 my testimony taken under oath in my
10 deposition of August 8, 2019; that the
11 transcript is a true and complete record
12 of my testimony, and that the answers on
13 the record as given by me are true and
14 correct.
15
16
17
18
19 Signed and subscribed to before me this
20 _____ day of _____, 2019.
21
22
23 Notary Public, State of
24

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1 C E R T I F I C A T E
2 STATE OF NEW YORK
3 COUNTY OF NEW YORK
4
5 I, Marie Foley, RMR, CRR, a
6 Certified Realtime Reporter and Notary
7 Public within and for the State of New
8 York, do hereby certify:
9 THAT LAWRENCE LIND, M.D., the
10 witness whose deposition is hereinbefore
11 set forth, was duly sworn by me and that
12 such deposition is a true record of the
13 testimony given by the witness.
14 I further certify that I am not
15 related to any of the parties to this
16 action by blood or marriage, and that I am
17 in no way interested in the outcome of
18 this matter.
19 IN WITNESS WHEREOF, I have
20 hereunto set my hand this 16th day of
21 August, 2019.
22
23
24

Lawrence Lind, M.D.

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